91-674

No.

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

Chaves County Home Health Services, Inc., et al

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v.

Louis W. Sullivan, M.D.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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Questions Presented

1. Whether the ruling of the Court of Appeals improperly expands the boundaries of statutory construction by the judiciary, as established by the Supreme Court in Chevron, by characterizing the Medicare Act as ambiguous regarding the authority of HHS to process medicare claims onother than an individual basis, while neglecting to analyze the language of the statute at issue. 42 U.S.C. §1395ff.

2. Whether the use of sampling review for post-payment adjudication of Medicare claims violates 42 U.S.C. §1395ff which provides that HHS process all claims of Medicare beneficiaries and health care providers, both initially and on appeal, on an individual basis.

3. Whether the Secretary's implementation of an unwritten post-payment sample review claims adjudication process, in the absence of compliance with the Administrative Procedures Act, 5 U.S.C. § 553, can be retroactively validated through the implementation of HCFA Ruling 86-1 under the Supreme Court's ruling in Bowen v. Georgetown University Hospital.

PARTIES

Petitioners

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Respondent

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Chaves County Home Health Services, Inc., Albuquerque Visiting Nurse Services, Inc., and Bayonne Visiting Nurse Association, Inc. petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The opinion of the Court of Appeals (App., *infra*, 1a-27a) is reported at 931 F2d 914 (D.C. Cir. 1991). The opinion of the District Court is reported at 732 F.Supp 188 (D.D.C. 1989).

JURISDICTION

The judgment of the Court of Appeals was rendered on April 26, 1991. A petition for rehearing and suggestion for rehearing *en banc* was denied on July 26, 1991. (App., *infra* , 1b). Jurisdiction of this Court is invoked pursuant to 28 U.S.C. 1254 (l).

STATUTORY PROVISIONS INVOLVED

The Medicare provisions of the Social Security Act, 42 U.S.C. §1395ff(a), provides in relevant part:

> Determinations of the Secretary
>
> (a) Entitlement to and amount of benefits. The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A or part B, and any other determination with respect to a claim for benefits under part A or a claim for benefits with respect to home health services under part B shall be made by the Secretary in accordance with regulations prescribed by him.
>
> As amended October 21, 1986, P.L. 99-509

Prior to the 1986 amendment, 42 U.S.C. §1395ff(a) provided:

> (a) Entitlement to and amount of benefits. The determination of whether an individual is entitled to benefits under part A or part B and the determination of the amount of benefits under part A, shall be made by the Secretary in accordance with regulations prescribed by him.

STATEMENT OF THE CASE

This case represents a challenge to the Secretary's use of a sample adjudication scheme to review Medicare claims for home health services benefits which had been previously paid by the Medicare program on behalf of individual patients of the petitioners.

Factual background

Petitions are non-profit organizations participating in the Medicare program as providers of home health services, 42 U.S.C. §1395x(o). Medicare makes available to beneficiaries extensive coverage of medically necessary home health services, including skilled nursing, therapy, and home health aide services. 42 U.S.C. §1395x(m).

The initial determination as to whether a claim on behalf of a home health services patient is covered under the Medicare program is delegated to outside government contractors, known as regional home health intermediaries, 42 U.S.C. §1395h. Each claim is processed individually by the intermediaries, and adverse determinations are subject to rights of appeal under 42 U.S.C. §1395ff(b).

None of the petitioners had demonstrated any history of submitting non-covered claims under Medicare as each had been awarded a favorable presumptive status under 42 U.S.C. §1395pp(f) by having a claim denial rate of less than 2.5 percent.

On March 8, 1984, December 28, 1984, and September 20, 1985, Albuquerque VNS, Chaves County, and Bayonne VNA, respectively, were notified that thousands of previously reviewed and paid claims had been readjudicated and denied. However, the intermediaries did not re-review the claims on an individual basis. Instead, the intermediaries substituted a small (as low as 3%) sample review in a post-payment readjudication of the claims which had been previously reviewed at a prepayment stage on an individual, claim-by-claim basis. The results of the sample review were projected to the universe of claims in issue.

Based upon those readjudications, the intermediaries, on behalf of the Secretary, demanded immediate repayment of $138,113.38 from Albuquerque VNS, $46,913.19 from Chaves County, and $1,506,639.00 from Bayonne VNA. The demand for repayment was for an immediate recoupment without postponement to accord the petitioners with any opportunity to seek review through the administrative appeals process.

Albuquerque VNS exemplifies the operation of sample adjudication. There, the intermediary examined only

200 claims of the 2,460 claims which had been previously reviewed on an individual basis and paid. This represented only 8% of the claims submitted between March 5, 1982 and March 25, 1983. Immediately after the coverage denials the Secretary began to withhold direct Medicare payments to collect the alleged overpayment. The VNS initiated administrative appeals, most of which were successful, but could not financially survive and declared bankruptcy on February 2, 1988.

All three petitioners contested the Secretary's authority to deny Medicare coverage through a sample adjudication scheme which supplanted the original determinations which individually found the claims as within Medicare requirements for payment. Petitioners also pursued appeals of the merits of the coverage determinations issued on the sample claims.

While administrative appeals were pending before administrative law judges (ALJ), the Secretary issued HCFA Ruling 86-1 (App., *infra* , 1c-c) which was binding on the ALJs and compelled them to reject jurisdiction over a challenge to the Secretary's use of a sample adjudication scheme. HCFA Ruling 86-1 was issued February 20, 1986.

The ALJ in the Albuquerque VNS case refused to be bound by HCFA Ruling 86-1 and held that the scheme violated numerous provisions of the Medicare Act and regulations. Subsequently, the Appeals Council, 42 CFR §405.724; 20 CFR §404.967, vacated the ALJ's ruling based upon the binding nature of HCFA Ruling 86-1.

The ALJs in the Chaves County and Bayonne VNA cases both ruled that HCFA Ruling 86-1 was binding upon them and that they were without jurisdiction to review its validity.

The administrative appeals process eventually led to the reversal of virtually all claim denials and a corresponding reverse extrapolation of the effect of sample adjudication. However, the appeals process highlighted the practical effect of sample adjudication as follows:

- Claims which had been previously reviewed on an individual basis were, in practical effect, denied through the projection of the sample results.

- Repayment of the projected claims denials was required prior to the completion of the administrative appeals process.

- Where individual claims in the sample did not meet the jurisdictional amount in controversy of $100 under 42 U.S.C. §1395ff(b), there was no right to a hearing despite the fact that the extrapolated effect of sample review incurred a repayment obligation in excess of a $100 amount in controversy. These home health agencies were permanently deprived of thousands of dollars in previously paid claims without a hearing through this element of the sample adjudication scheme.

- The appeals process has yet to be completed on some claims over 5 years after the original denials.

- Rights of appeal available only subsequent to a repayment obligation, combined with the risk of erroneous coverage determinations forced Albuquerque VNS into bankruptcy on February 22, 1988 after 35 years of service within its community.

Proceedings below

On September 29, 1986, litigation was commenced in the United States District Court for the District of Columbia, *Chaves County Home Health Services, Inc., et al* v. *Bowen*, Civil Action No. 86-2691. Ultimately, the district court denied defendant's motion to dismiss for lack of subject matter jurisdiction, denied plaintiff's motion for summary judgment and granted defendant's motion for summary judgment. 732 F.Supp 188 (D.D.C. 1989). The general basis for the district court's ruling was a reliance upon the broad powers of the Secretary to make adjustments in payments pursuant to 42 U.S.C. §§1395g(a); 1395u(a);

1395x(v)(1)(A)(ii), *Chaves County Home Health Services, Inc.*, v. *Sullivan*, 732 F.Supp 188 (D.D.C. 1990).

On appeal to the Court of Appeals for the District of Columbia Circuit, the panel affirmed the district court's rulings on other grounds. 921 F.2d 914 (D.C. Cir. 1991). The Court of Appeals rejected the district court's statutory basis, Id. at 918; App., *infra*, 8a. However, the Court held that the ambiguity of the Medicare Act relative to the Secretary's authority to engage in sample adjudication combined with deference to the Secretary's interpretation under the standard enumerated in *Chevron U.S.A., Inc.* v. *National Resource Defense Council*, 467 U.S. 837 (1984) justified an affirmance of the result.

The Court of Appeal found that "sample adjudication is not, however, a determination that some particular though unidentified claims outside that sample should have been denied; instead it is a monetized estimate of the scope of a provider's overcharges from a sample." Id. at App., *infra*, 15a. The Court suggested that providers could remedy its harm by directly billing beneficiaries who had been previously on notice that their services were noncovered or appeal the sample determination by establishing that all claims in the universe actually satisfied Medicare coverage standards thereby demonstrating the invalidity of the denial projection. Id. at App., *infra*, 15a. No such opportunity exists either practically or within the jurisdiction of an appeals process.

REASONS FOR GRANTING REVIEW

I. *The Court of Appeals Has Created A New Standard Of Statutory Construction In Failing to Analyze the Language of the Statute at Issue.*

Under 42 U.S.C. §1395ff(a), the Medicare Act definitively requires that all determinations regarding coverage of home health services must be rendered by the Secretary on an individualized, claim-by-claim basis. Here, the Court of Appeal's ruling is subject to a fatal flaw: the Court has failed to even reference the statute at issue, let alone analyze its language. As such, the Court's ruling is directly contrary to the well established principles of statutory construction which require that the first step in the analysis is the statutory language itself. *Chevron U.S.A., Inc. v. National Resources Defense Council,* 467 U.S. 837, 843-844, 104 S.Ct. 2778, 2781-2; 81 L.Ed. 2d 694, 703 (1984).

The Court of Appeals' ruling is founded on a single, guiding conclusion that the statute is ambiguous or silent relative to the authority of the Secretary to engage in sample claim adjudication. This finding led to the premature and unnecessary analysis of whether the agency's interpretation of the statute represented a permissible construction or one which is arbitrary and capricious. *Chevron*, supra at 843-84.

While the Court of Appeals found nothing in the statute expressly allows or disallows sample audits, App., *infra*, 5a, court utterly failed to analyze 42 U.S.C. §1395ff(a) which requires that all claims be determined on an individual basis exclusively. Specifically, 42 U.S.C. §1395ff(a) requires the Secretary to issue determinations "of whether an individual is entitled to benefits . . . (emphasis added). It is the clear exclusivity of the *individual* claim determination process which precludes the use of sample adjudication.

The Court of Appeals' failure to even note the statute deemed ambiguous creates a dangerous precedent, at odds with all

decisions of the U. S. Supreme Court establishing the principles of statutory construction. If left undisturbed, this ruling creates a license for the federal court to ignore Congressional mandates, overturn agency interpretations, and substitute its own policy choices under the guise of statutory ambiguity. It is the power of Congress to legislate. Administrative agencies implement legislative acts through regulation. The judiciary is responsible for determining what a law means. *Chevron*, supra at 843 fn 9. The courts should not be allowed to usurp the role of Congress and administrative agencies through the use of unfocused, undefined power to declare a statute ambiguous.

It is crucial that this Court intervene to stem this judicial activism through the reinforcement of its longstanding principles of statutory construction. Here, it is not the statute governing the Secretary's process for Medicare claim determinations that is ambiguous. Rather, it is the ruling of the Court of Appeals that is silent as to the statutory and regulatory basis for its decision.

The Supreme Court's well-settled principles of statutory construction require that:

> When a court reviews an agency's construction of the statute it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the Court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the Court determines Congress has not directly addressed the precise question at issue, the Court does not simply ignore its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Chevron, U.S.A., 467 U.S. at 842-843; 104 S.Ct. at 2781-2; 81 L.Ed. 2d at 702-3. (footnotes omitted)

While debate has raged concerning a proper meaning of the term "ambiguous", *See*, Sunstein, *Law and Administration After Chevron*, 90 Colum. L. Rev. 2071, 2091-2093, there is no dispute that resolution of conflict regarding the meaning of a law must begin with the statutory language itself. *Schreiber v. Burlington Northern, Inc.*, 472 U.S. 1,5; 105 S.Ct. 2485, 2461; 86 L.Ed. 2d 1, 5-6 (1985). "In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291, 108 S.Ct. 1811, 1817; 100 L.Ed. 2d 313, 324 (1988).

The Supreme Court has successfully preserved this principle of statutory construction over the years. Regardless as to whether the Court ultimately accepted or rejected a federal agency's interpretation of the law, the Court has always begun its analysis with the language of the statute to determine Congressional intent and the extent of delegated administrative authority to interpret the law. *See*, e.g., *Rust v. Sullivan*,___U.S.___; 111 S.Ct. 1759 L.Ed. 2d 72(1991)(review of the term "method of family planning" under 42 U.S.C. §300a-6a regarding the limitation of use of federal funding for abortion counseling, referral, and advocacy); *Sullivan v. Everhardt*, ___U. S. ___; 108 S.Ct. 960; 108 L.Ed. 2d 72 (1990) (authority of Secretary to make "proper adjustment or recovery" when he "finds that more or less than the correct amount" of "payment" has been made under 42 U.S.C. §404(a)(1)(A),(B)(1982 ed. Supp. IV)); *Dole v. United Steelworkers of America*, ____U.S.___; 110 S.Ct. 929; 108 L.Ed. 2d 23 (1990)(interpretation of terms "information collection request" and "collection of information" defined as "the obtaining or soliciting of facts by an agency through . . . reporting or recordkeeping requirements" under the Paperwork Reduction Act, 44 U.S.C. §3502); *Sullivan v. Zebley*, ___U.S. ___; 110 S.Ct. 885; 107 L.Ed. 2d 967(1990)(meaning of "comparable severity" of child's disability in relation to adult's disability under 42 U.S.C. §1382(c)(a)(3)).

In fact, the Supreme Court has often turned to dictionary definitions of terms in order to understand their meaning and the potential for ambiguity. *See*, e.g., *Pittston Coal Group v. Sebben*, 488 U.S. 105, 113; 109 S.Ct. 414, 420; 102 L.Ed. 2d 408, 420 (1988), reference to Webster's Ninth Collegiate Dictionary for definition of "criteria"). A law cannot be considered ambiguous without reference to the language at issue.

The Court of Appeals' ruling is utterly devoid of any reference to the statutory provision deemed ambiguous. Instead, the Court of Appeals refers to statutory provisions which it concludes as inapplicable and others which provide authority for the recovery of overpayments, but not the process for determining whether an overpayment has been made. This deficiency in the Court of Appeals' analysis is highlighted in its review of HCFA Ruling 86-1 (App. *infra*, 8a). It was HCFA Ruling 86-1 which the Secretary claimed as the explanation of the authority for the policy on sample adjudication.

The Court of Appeals rejected the Secretary's claimed statutory authority. In finding the cited authority, 42 U.S.C. §1395g(a); 1395u(a); 1395x(v)(1)(A)(ii), governed reasonable cost determinations rather than the issues of coverage determinations presented in Petitioner's claim, the Court concluded that "we do not read these provisions as explicit statutory authorization for sample adjudication or post-payment review of coverage determinations." App. *infra*, 8a. The Secretary has never offered any other statutory basis, ambiguous or otherwise, for the alleged authority to engage in sample adjudication.

The Court of Appeals' difficulty with the issues is due to efforts to locate statutory language which "expressly disallows" sample adjudication. App. *infra*, 5a, 6a. In attempting to find a statutory preclusion for sample adjudication, the Court ignored the single statutory provision which establishes the authority of the Secretary regarding the method and process of coverage claim determinations. 42

U.S.C. §1395ff(a). As discussed below, Section 1395ff(a) is the exclusive method and process for issuance of any determination affecting coverage of home health services under Medicare Part A. Section 1395ff(a) controls the process of determinations by the Secretary, precluding sample adjudication, not by way of explicit exclusion, but by limiting the authority of the Secretary to the issuance of individualized determinations exclusively.

To maintain the integrity of the principles of statutory construction, the Court of Appeals must examine the language of 42 U.S.C. §1395ff(a), apply the plain meaning of that language, analyze the provision in its overall context of the Medicare program, and determine then whether the statute is ambiguous. The Court of Appeals missed the first step, and as a result, stumbled through the remaining components of the process.

The Court of Appeals' method of statutory construction has broad implications within Medicare and well beyond. If a court can proceed to a Chevron step two analysis, *Chevron*, 467 U.S. 837, 843 (1984) without reference to the language of the statutory provision at issue, no act of Congress is sacred. Likewise, the *Chevron* step two analysis provides the vehicle for a court to reject an administrative regulation as unreasonable or arbitrary and capricious thereby further dismissing the intent of Congress and the expertise of the administrative agency. Effectively, the rule of statutory construction devised by the Court of Appeals creates the opportunity for policy making and legislating with the judicial branch.

An application of the method of statutory construction employed by the Court of Appeals to recent cases decided by the Supreme Court highlights the dangers attendant to a standard which does not focus on the statutory language as its starting point.

In *Dole v. United Steelworkers of America*, ___U.S.___; 110 S.Ct. 929; 108 L.Ed. 2d 23 (1990), the Secretary of Labor withdrew a Hazard Communication Standard which

imposed disclosure requirements which were designed to ensure that employees were informed of potential hazards posed by chemicals in the workplace. The Standard had been submitted to the Office of Management and Budget (OMB), for review under the Paperwork Reduction Act of 1980, 44 U.S.C. §3501, *et seq.* OMB disapproved three of the standards based on its determination that the requirements were not necessary to protect employees. The Secretary, despite her disagreement with OMB's assessment, published a notice in the *Federal Register* withdrawing the three standards at issue. The question ultimately presented to the Court was whether OMB had authority under the Paperwork Reduction Act to review and countermand agency regulations mandating disclosure by regulated entities directly to third parties.

As appropriate under existing standards of statutory construction, the Supreme Court turned to the language of the Paperwork Reduction Act to determine the authority of OMB on the issue presented, The Court found that,

> "No provision of the Act expressly declares whether Congress intended the Paperwork Reduction Act to apply to disclosure rules as well as information gather rules." *Id.*, 110 S.Ct. at 934; 108 L.Ed. 2d at 32.

In the absence of explicit inclusion or exclusion of disclosure rules, the Court proceeded to examine the language of the statute itself. 44 U.S.C. §§3502(ii), 3502(4)(1982 ed. Supp. V). A detailed analysis ensued with the Court applying a "common sense" reading standard of such terms as "reporting or recordkeeping requirements", "solicit", "obtain", and "records". 110 S.Ct. at 934; 108 L.Ed. 2d at 33-34. The Court reinforced its interpretation of these terms through consideration of the object and structure of the Act as a whole. 110 S.Ct. at 934; 108 L.Ed. 2d at 34. Ultimately, the Court declined to defer to OMB's interpretation of the Act, as found in federal regulation, based upon its findings "that the statute, as a whole, clearly expresses Congress' intention." 110 S.Ct. at 938; 108 L.Ed. 2d at 38.

If the Court in *United Steelworkers* had ignored the language of the Paperwork Reduction Act following its finding that the Act did not *expressly* apply to disclosure rules, deference to OMB regulations would have likely affirmed OMB's claimed authority to reject agency regulations mandating disclosures by regulated entities to third parties. Under the agency deference standard set out in *Chevron*, 467 U.S. 842-845, the dissent in *United Steelworkers* concludes that the OMB's interpretation is reasonable and therefore valid. 110 S.Ct. at 40 (White dissenting).

As with the Paperwork Reduction Act regarding its application to disclosure rules, no provisions of the Medicare Act "expressly declares" whether sample adjudication is prohibited or permitted. *Chaves*, App. *infra*, 5a. Nonetheless, instead of proceeding to examine the statutory language in 42 U.S.C. §1395ff(a) setting forth the Congressional mandate relative to claim determinations, the Court of Appeals here simply labeled the Medicare Act ambiguous and deferred to the Secretary's policy interpretation, set out in HCFA Ruling 86-1.

Under the Court of Appeals' standard, the Supreme Court ruling in *Sullivan v. Zebley*, ___*U.S.* ___ ; 110 S.Ct. 885; 107 L.Ed. 2d 967 (1990) is equally vulnerable. In Zebley, the Court invalidated regulations which restricted the parameters for review of a claim for child's disability benefits under the Supplemental Security Income Program (SSI) Title XVI of the Social Security Act, as added 86 Stat. 1465, and amended, 42 U.S.C. §1381 *et seq.* (1982 ed. and Supp. V). The Court concluded that the child-disability regulations could not be reconciled with the language of the authorizing statute.

At issue in *Zebley* was the meaning of the phrase "any medically determinable physical or mental impairment of comparable severity" under 42 U.S.C. §1382c(a)(3). The Social Security Act had defined "disability" in reasonable detail relative to individuals over the age of 18. A child under 18 was considered disabled if he/she met the standards developed under the parenthetical phase set out above.

The Secretary implemented §1382c(a)(3) through a series of regulations which establish a five step test of disability for adults and an abbreviated version for children, limiting the analysis to the first three of the five step adult disability test. Under the fourth and fifth steps of the adult test, the Secretary reviewed whether the claimant could perform his/her past work or any other work in the economy, in view of his age, education and work experience. No comparable analysis existed for review of a child's disability.

The Court rejected the regulations through an application of the statutory language to the regulations, finding that limiting the disability determination to a three step test resulted in a standard more severe than that set out in the statute. 110 S.Ct. at 896. The child disability standards were not "comparable" if they acted to exclude individuals who, as adults, could qualify for benefits under the fourth or fifth step of the adult disability test. The Court dismissed the Secretary's contention that a vocational analysis (a component of the fourth and fifth step) is inapplicable to children since they have not worked, finding that a comparable functional analysis could be applied. *Ibid.* Since the child disability analysis was "manifestly contrary to the statute," the Court accorded no deference to the Secretary's interpretation. 110 S.Ct. at 897.

Under the Court of Appeals' standard of statutory construction at issue here, the Supreme Court would have likely found the statute of concern in *Zebley* ambiguous and then deferred to the Secretary's interpretation unless that interpretation was determined arbitrary or capricious. While such conclusion might be considered speculative, a finding of ambiguity in the statute was the basis for the dissenting position that the regulations were valid. 110 S.Ct. at 898 (White dissenting). The statute did not explicitly require that the Secretary consider "nonmedical factors" or "specific consequences that an impairment must or should produce." *Ibid.* However, the Court instead met its responsibility of examining statutory language directly and in its overall context to integrate the reference of "comparable severity"

with the complete elements of a disability determination operative for adult claimants. If the Court of Appeals' standard had been applied, the Court's statutory analysis in *Zebley* would have ended when no specific inclusion of a functional analysis was found.

Here, the Medicare Act never uses the phrase "sample adjudication" or an equivalent within any statutory provision. However, the absence of specific terms on phrases from statutory language does not demonstrate, *per se*, that the statute is ambiguous relative to the authority of an administrative agency. For example, while 42 U.S.C. §1395ff(a) references "determinations" of the Secretary as subject to appeal, the Secretary cannot deny an appeal to an aggrieved claimant simply by labeling an action of the Secretary as a "decision" instead of a "determination." The Court of Appeals' standard for review as to whether a statute is ambiguous completely ignores the language of the statute and the meaning of the words within a statute. Under 42 U.S.C. §1395ff(a), sample adjudication is expressly excluded through the manifestly clear limitation of the Secretary to issue individual determinations exclusively.

To allow the Court of Appeals to maintain a standard of statutory construction which does not begin with the language of the statute and which instead requires that Congress enact the exact words or phrases at issue in the action before the court is a disastrous precedent. Had the Supreme Court in *United Steelworkers* and *Zebley* applied a similar standard, the intent of Congress would not have been honored. Congress cannot be held to a standard of statutory drafting which requires it to use each and every potentially applicable word in the English language to ensure that the legislative intent is followed.

If Congress were to mandate that all paper currency must be printed with green ink, its intent would not be ambiguous simply because it did not specifically state that the currency could not be printed in red, blue, yellow or any other existing color. However, to determine whether Congress would allow for other ink colors to be used in combination with

green, the courts would need to examine the language of the statutory provision to determine whether the plain meaning of the law would allow such interpretation.

Alarmingly absent from the Court of Appeals' analysis is any review of its language of 42 U.S.C. §1395ff, the sole provision of the Medicare Act which establishes the authority of the Secretary to issue claim determinations under Medicare Part A. If the Court of Appeals can adjudge the clarity or ambiguity of Congressional intent without reference to the language of the statute, then no act of Congress is safe from arbitrary judicial rejection.

The dire consequences of the Court of Appeals' approach can also be felt within the administrative agencies. A finding of statutory ambiguity leads to review of an agency policy or regulations under a test of reasonableness. *Chevron*, supra at 843-44. Within this step of the analysis, a court has the opportunity to substitute its own consideration of reasonable policy for that of the administrative agency. Failure to analyze the pertinent statutory language is the equivalent of attempting to determine Congressional intent in a vacuum. The Court of Appeals has failed to adhere to the most basic test of statutory construction: the "starting point is the language of the statute." *Schreiber v. Burlington Northern, Inc.*, 472 U.S. 1,5; 105 S.Ct. 2458, 2461; 86 L.Ed. 2d 1, 5-6 (1985).

II. *The Court of Appeals Ruling Has Broad Ramifications Within the Medicare Program Through Validation of Sample Claims Adjudication which Violates the Rights of Beneficiaries and Providers to Individualized Claims Determinations and Appeal..*

The natural and forseeable effect of sample adjudication in Medicare is fear. The extrapolated effect of a single claim denial in a process of sample adjudication can be thousands of dollars. For home health agencies, operating on "reasonable cost" reimbursement, 42 U.S.C. §1395x(v), there is literally no profit, no margin in Medicare revenue that can be used to offset a monetary recovery occasioned by retroactive claims denials in a sample adjudication system. With most home health agencies relying upon cost-based payments from Medicare and Medicaid (Title XIX of the Social Security Act, 42 U.S.C. §1396 *et seq.*) repayment of an alleged overpayment is nearly impossible. The costs of providing any non-covered care have already been incurred. Recourse to recovery from the patient is generally unavailing as many may not be still alive, let alone with sufficient funds at the time of sample adjudication.

However, this is not a case where providers of home health agencies are screaming foul because they stand to lose money in a government financed health care program. Likewise, it is not an attempt by providers to take advantage of a gigantic health insurance program that cannot afford to pay attention to little details as required in a claim-by-claim adjudication program. Instead, it is a case concerning the integrity of the Medicare program wherein the beneficiaries are guaranteed the right to be treated as individuals, with unique conditions and needs requiring health care services. It is a case involving rights of beneficiaries and providers alike to fair notice and appeals. Most importantly, it is a case which seeks to ensure that the Congressional goal of access to health care for this nation's elderly and disabled is not obstructed by a fear inducing device known as sample adjudication.

To understand the environment of fear created by sample adjudication and its disastrous effect on access to home health services under Medicare, four factors must be understood. First, under Medicare's waiver of liability provision, 42 U.S.C. §1395pp, a retroactive claim denial can shift liability for the cost of services already rendered from Medicare or the beneficiary to the provider of care. Second, historically, the Medicare administration has demonstrated that the risk of an erroneous coverage denial by its fiscal intermediaries is very high. Third, an error in a claim determination by the intermediary is exponentially magnified through a system of sample adjudication. Fourth, the provider of services can only reduce its risk of shifted liablity through restricting access to care for beneficiaries.[1]

This environment of fear and the resulting "chilling effect" on access to care is not mere speculation offered to justify this Court's granting of the petition for writ of certiorari. Rather, it is based upon historical facts which demonstrated that home health agencies and their patients are ready victims to arbitrary claims determinations by the Medicare program.

In the mid-1980's, the Medicare home health benefit was under attack and was at risk of total dismantling. Coverage denials had skyrocketed and home health agencies were providing care, not in accordance with patient needs, but in

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[1] It must be understood that home health agencies are not challenging sample adjudication to retain Medicare payment for non-covered services. Instead, the challenge is an effort to curtail the magnification of erroneous coverage denials where the Secretary recoups alleged overpayments prior to the opportunity of the home health agencies to reaffirm the actual coverage of the services at issue which had been established at initial prepayment review.

conformity with erroneous and arbitrary coverage determinations by Medicare intermediaries. The program was in shambles.[2]

In order for the organizations to survive and provide some care to home care patients, the home health agencies ran scared from the Medicare program. Their greatest fear was the risk of shifted liability under 42 U.S.C. §1395pp for a retroactive coverage denial which would lead to a reimbursement recovery of Medicare payment for costs already incurred. The appeals process was available, but of little solace since a hearing before an administrative law judge under 42 U.S.C. §1395ff(b) came one to two years after the coverage denial. The only other recourse was to reduce services and access to care for Medicare beneficiaries in an effort to reduce the volume of arbitrary coverage denials. This "chilling effect" was both obvious and forseeable.

On March 17, 1987, a coalition of Medicare beneficiaries, United States Congressmen, and home health agencies filed a nationwide class action lawsuit challenging Medicare's decisionmaking process, *Duggan, et al. v. Bowen*, Civil Action No. 87-383-SS, (D. D.C.). Following a court ruling on one of the claims presented, *Duggan*, 691 F. Supp. 1487 (D.D.C. 1988), the parties proceeded to settlement wherein coverage standards were clarified and re-written. That settlement process continues today with a recently published Notice of Proposed Rulemaking concerning the home health services benefit coverage criteria. 56 Fed. Reg. 49154 (September 27, 1991).

The preamble to that proposed rule sets out the overriding principle of Medicare coverage determinations:

> "A coverage denial may not be made solely on the basis of the reviewer's general inferences about

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2 *See generally*, GAO Report, No. HRD-90-14BR (January 24, 1990. Subject: Increase Denials of Home Health Claims During 1986 and 1987, CCH Medicare and Medicaid Guide, ¶ 38,386.

> patients with similar diagnoses or on data related to utilization generally, but must be based upon objective clinical evidence regarding the *patient's individual need* for care. Hence, each decision as to whether care is reasonable and necessary, as required by section 1862(a)(1)(A) of the Act, is *unique* in that it hinges upon the condition of a *specific beneficiary*." 56 Fed. Reg. at 49160 (emphasis added).

The use of a sample adjudication process is not simply a "monetized estimate of the scope of a provider's overcharge derived from the sample." *Chaves County*, App., *infra*, 15a. Instead, it is a blatant rejection of Medicare's longstanding principle which recognizes that the health care needs of the Medicare beneficiary and right to coverage depends upon his/her unique and specific condition. While the Court of Appeals recognized the importance and value of this right to an individualized determination at the pre-payment stage, App., *infra*, 6a, it eradicates that right in ruling that sample adjudication can supplant individual coverage determination on post-payment review. The guarantee of individual determinations is thereby rendered meaningless and can only be viewed as a sham.

The Court of Appeals' ruling cannot be considered as one supported by deference to the interpretation of law by an administrative agency. Rather, it is judicial policymaking in full fever. First, the Court ignores the only statutory provision which governs coverage determinations affecting home health services, 42 U.S.C. §1395ff(a). Second, the Court creates out of thin air a distinction between the process of pre-payment and post-payment determinations. App., *infra*, 6a, 11a, 13a. Third, the Court premises its analysis on the so-called "logic of sample adjudication" referencing unrelated cases in other contexts which involved the use of statistical sampling. App. *infra*, 10a. The Court's review is akin to that of a legislative committee debating the merits of a proposal for legislation rather than that of a court attempting to interpret Congressional intent.

The sole governing authority with respect to the process that the Secretary must employ regarding coverage determination is set out in 42 U.S.C §1395ff(a). In pertinent part, it provides:

> The determination of whether an individual is entitled to benefits under Part A or Part B and the determination of the amount of benefits under Part A or Part B, and any other determination with respect to a claim for benefits under Part A or claim for benefits with respect to home health services shall be made by the Secretary in accordance with regulations prescribed by him.

42 U.S.C. §1395ff(a).

Notably, the Court of Appeals fails to reference the provision, in whole or in part, at any point in its ruling. It is difficult to understand how the Court could reach any conclusion without any analysis of this relevant portion of the Medicare Act.

The Court states that sample adjudication on initial review of payment claims would be inconsistent with the statute. App., *infra*, 6a. It further finds that the "process of reviewing initial payment claims requires particularized decisions," but then questions "whether the same rights to individualized factual determinations and an opportunity to challenge specific denials are at stake on post payment review." App., *infra*, 12a. Highlighting its distinction between pre-payment and post-payment determinations is the here-to-before unknown concept of a "reconsideration of approvals" in contrast to reconsideration of initial claim denials. App., *infra*, 13a. This entire system has been created by the court using language which appears nowhere in the Medicare Act and without reference to any relevant statute or regulation.

The essential problem the Court of Appeal has in its analysis is the failure to distinguish between the *standards* for Medicare benefits and the *process* for issuance of coverage determinations. The Court of Appeal continually confuses the

powers of the Secretary to deny payment for unnecessary care, 42 U.S.C. §1395y(a), recover overpayments, 42 U.S.C. §1395gg, or shift payment liability to beneficiaries and providers, 42 U.S.C. §1395pp, with the authority of the Secretary to implement a process to reach the substantive determinations. Petitioners have not disputed the power of the Secretary to recover overpayments. Instead, the controversy concerns the process of determinations that must be utilized by the Secretary to find that an overpayment has been made. Section 1395ff(a) unambiguously requires that the Secretary employ a process of individualized determinations for all substantive decisions.

The Secretary's claimed statutory authority for a method of sample adjudication for the process of claims determinations is set out in HCFA Ruling 86-1. The Court of Appeals summarily rejected this alleged authority finding that the provisions cited "deal with 'reasonable cost' rather than 'coverage determinations'." App., *infra,* 8a. The Secretary has cited 42 U.S.C. §1395g(a) which establishes the process for the Secretary to determine the amount of payment owing to a provider of services. Accordingly, the Secretary has recognized the distinction between statutory powers relative to substantive determinations and the process that must be followed in the issuance of the determination.

When the Court rejected the Secretary's claimed statutory authority for the process of coverage determination, it failed to fill the vacuum with an analysis of section 1395ff(a). However, Congress did not create a void in its statutory design.

Section 1395ff(a) represents a crucial component of an integrated system of Medicare coverage determinations which relies upon a unitary process of decisionmaking to coordinate the variety of substantive determinations delegated to the Secretary. For example, 42 U.S.C. §1395y(a)(1) excludes coverage of items and services which are not reasonable and necessary. Section 1395y(a)(1) itself, by its language or operation, does not establish the process for issuance of a determination relative to the standard of "reasonable and

necessary." That process is set out in section 1395ff(a) which governs all determinations with respect to benefit claims.

Similarly, 42 U.S.C. §1395gg authorizes the Secretary to recoup overpayments from beneficiaries and providers. No process for issuing the necessary determinations that benefits have been overpaid is set out in section 1395gg. Instead, the Secretary must find authority for the process of issuance of overpayment determination under section 1395ff(a). A finding that an overpayment has occurred presupposes the issuance of a determination that more than the correct payment has been made. If section 1395ff(a) did not exist, perhaps the Secretary could find some basis for implied authority. However, for section 1395ff(a) to serve any purpose, it must control the process of such determinations.

The integration of substantive rights and responsibilities within a single, unitary process of claim determinations is mmost evident relative to the rights of appeal from Medicare beneficiaries and providers. Those rights of appeal are set out in 42 U.S.C. §1395ff(b) which is triggered only through the issuance of a determination under section 1395ff(a). In the absence of a subsection (a) determination, there can be no appeal.[3] Certainly, allowing the Secretary to create a process for issuance of claim determinations independent of section 1395ff(a) would be illogical given the resultant loss of any statutory rights of appeal.

The Secretary has implemented section 42 U.S.C. §1395ff(a) in a manner which recognizes that all determinations, including matters related to coverage,

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[3] Providers of services maintain a right of appeal separate from beneficiaries by virtue of 42 U.S.C. §1395pp(d) which accords providers the same rights that an individual has under section 1395ff(b). However, a pre-condition to these rights of appeal remains the issuance of a determination pursuant to the process under section 1395ff(a). for issuance of claim determinations independent of section 1395ff(a) would be illogical given the resultant loss of any statutory rights of appeal.

overpayments, and waiver of recovery or adjustment are subject to the same claim determination process. 42 CFR §405.704. No distinction is process is drawn between pre-payment and post-payment determinations. This process has existed since the inception of the Medicare program. It contains no reference to sample adjudication or any basis for the creation of such by way of implication.[4]

Harm abounds through the process of sample adjudication. The "chilling effect" created in an environment where any error of the Secretary is magnified exponentially and the appeal system that is available to correct errors is not expeditiously accessible is readily apparent. The most sensible recourse for providers is to narrow the margins for error by restricting access to care. While the restriction may eliminate non-covered care, it will also extend to services that would be covered under an accurate claim determination by the Secretary.

Petitioner Albuquerque Visiting Nurse Service best exemplifies the consequences for health care providers who do not respond to the threatened effect of sampling. Due to its inability to pay back alleged overpayments, it has ceased operation and is no longer an available health care resource in New Mexico.

The Medicare system itself is also at risk with sample adjudication. The recognition of the Medicare beneficiary as unique in terms of individual medical need is eliminated from the process of claims determinations. The individualized claim determination process which the Court of Appeals found required under the Medicare Act is rendered meaningless by post-payment claim adjudication. A pre-payment decision made on the basis of the patient's unique condition is eradicated by a post-payment determination based upon other standards applied the following day.

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[4] The Court of Appeals reference to a sample adjudication policy from the *Medicare Intermediaries Manual*, App., *infra*, 20a , is misleading. This policy was issued subsequent to HCFA Ruling 86-1.

Each claim of every home health agency is subject to a individualized review prior to payment by Medicare. Sample adjudication re-reviews only a small portion of these same claims yet the accuracy of unidentified claims which had been individually reviewed is called into question. It strains logic to consider that a claim specifically reviewed and determined payable could be supplanted with a sample adjudication projection where no element of the claim is reviewed.

The Secretary has continually argued that this case does not concern beneficiaries. However, that short-sighted view ignores the partnership between the care provider and the patient in the health care spectrum and the intimate relationship between services and payment. The Court of Appeals' ruling has direct application to Medicare beneficiaries in that it provides authorization for the Secretary to create a separate post-payment claim determination process devoid of the Congressionally mandated notice under 42 U.S.C. §1395h(j)(1), the rights of appeal under 42 U.S.C. §1395ff(b), and the well-established principles of individualization. Providers of services also lose these protections which are integral elements of their partnership with patients. Sample adjudication is only one method of alternative claims processing that the Secretary can employ. While it might never be used directly against beneficiaries, the principle of law espoused by the Court of Appeals allows the Secretary to create any other method of post-payment claim adjudication process he believes reasonable which does not involve individualization of claims review.

Congress has made its choice through enactment of 42 U.S.C. §1395ff(a). The Secretary has usurped the power of Congress in creating an alternative system of claims processing. The future of the Medicare program and its goal to provide access to health care services is now in jeopardy.

III. *TheCourt of Appeals' Ruling Encourages Retroactive Rulemaking To Validate Past Conduct of An Agency.*

The mystical method of statutory construction employed by the Court of Appeals is reapplied in comparable form in its review of Petitioners' claim under the Administrative Procedures Act, 5 U.S.C. §553. At the heart of the determination of whether a rule is exempt from public notice and comment is whether the rule has the force and effect of law, i.e., it is binding on the decisionmaker. *Batterton v. Marshall*, 648 F.2d 694, 705 (D.C. Cir. 1980); *Gibson Wine Co. v. Snyder*, 194 F.2d 329 (D.C. Cir. 1952). However, the Court of Appeals found HCFA Ruling 86-1 to be "interpretive" despite the unambiguous language of the rule that it is binding, App., *infra,* 19a.

Similarly, the Court of Appeals found that HCFA Ruling 86-1 was "not the source of administrative authority," App., infra, 18a. This conclusion is in direct conflict with the actions of the Administrative Law Judge and the Appeals Council preceding this litigation where the claims of the Petitioners were rejected solely upon the basis of HCFA Ruling 86-1.

The Court's crucial error is its unsupported finding that the Secretary's policy of sample adjudication was longstanding. App., *infra,* 18a.[5] However, as late as 1986, the General Accounting Office indicated the Secretary has no sampling adjudication process for Medicare Part A. GAO Report No. HRD 87-9.

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[5] The Court's reliance on *Mount Sinai Hospital* v. *Weinberger*, 517 F.2d 329, modified, 522 F.2d 179 (5th Cir. 1975), cert. denied, 425 US 935 (1976) is grossly misplaced. *Mount Sinai* Hospital did not involve the validity of sample adjudication and occurred prior to the enactment of legislation which afforded due process rights to providers of care, 42 U.S.C. §1395pp, as added October 30, 1972, P.L. 92-603, Title II, §213(a), 86 Stat. 1384.

The result of the Court's erroneous findings is the creation of a new standard in determining whether a rule is impermissibly retroactive under *Bowen v. Georgetown University Hospital*, 488 US 204; 208-213, 109 S.Ct. 468, 471-74; 102 K,Ed, 2d 493, 499-503 (1988). Under the Court of Appeals standard, a rule is valid if it is created after the completion of unauthorized actions which are the subject of the rule, but prior to the initiation of litigation in federal court to challenge the action.

If this Court allows the ruling to stand, administrative agencies will be authorized to retroactively validate administrative action under the claim that it is written policy which "merely explained and reaffirmed" longstanding practice. 931 F.2d at 923. The only instance of Medicare Part A claim sample adjudication prior to the matters at issue herein was in Mount Sinai Hospital where the relevance is extremely suspect. (See footnote 4).

An isolated, and likely irrelevant, prior use of a challenged practice does not constitute a longstanding policy. If such practice were so well-established, HCFA Ruling 86-1 would be unnecessary, certainly not to the extent to label it as binding within the Medicare program.

The Secretary's issuance of HCFA Ruling 86-1 is remarkably similar to Medicare' actions in *Georgetown University Hospital*. In both instances, the Secretary implemented a written rule which attempted to retroactively validate or authorize an action which was desired, but had not been authorized at the time the action occurred.

Allowing the Court of Appeals' ruling to stand will encourage administrative agencies to develop practices without written authority. If the agency escapes challenge in a single use of the practice, written rules would retroactively validate the practice when a challenge arises. By failing to commit its practice to a written rule prior to original use, the agency improves its chances that its intentions will avoid scrutiny. With such procedures, advance public notice and

opportunity to comment -- the essential purpose of the A.P.A. -- will be lost.

CONCLUSION

The questions presented to the Court in this Petition fit squarely within the considerations governing review or writ of certiorari as set forth in Rule 10 of the Revised Rules of the Supreme Court of the United States (1990). The standard of statutory construction employed by the Court of Appeals establishes a dangerous precedent which creates the opportunity for courts to disregard statutory language and to substitute a judicial ruling for legislative enactments and administrative rules.

The specific Medicare issues involved in sample adjudication also represent special and important questions of federal law which have significant impact on the operation of the primary health insurance program for this nation's elderly and disabled. Finally, the ruling dismantles the Administrative Procedures Act by permitted retroactive rulemaking under the guise of a claim that the rule merely memorializes the basis for the agencies' past conduct.

The ruling is at odds with well-established precedent of this Court. Moreover, the issues presented involve vital elements of the administration of Medicare. For these reasons, and those set out in detail above, the Petitioners respectfully request that this Court grant review.

Respectfully submitted,

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October 1991

APPENDIX A

Notice: This opinion is subject to formal revision before publication in the Federal Reporter or U.S.App.D.C. Reports. Users are requested to notify the Clerk of any formal errors in order that corrections may be made before the bound volumes go to press.

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 22, 1991 Decided April 26, 1991

No. 90-5100

CHAVES COUNTY HOME HEALTH SERVICE, Inc., *et al.*

APPELLANTS

LOUIS W. SULLIVAN, M.D., SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Appeal from the United States District Court for the District of Columbia

(Civil Action No. 86-02691)

James C. Pyles, with whom *Barbara S. Woodall* was on the brief, for appellants.

Robert M. Loeb, Attorney, Department of Justice, with whom *Stuart M. Gerson*, Assistant Attorney General, *Jay B. Stephens*, United States Attorney, *Barbara C. Biddle*, Attorney, Department of Justice, and *Henry R. Goldberg*, Counsel, Department of Health and Human Services,

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

were on the brief, for appellee. *John C. Hoyle*, Attorney, Department of Justice, also entered an appearance for appellee.

Before: MIKVA, *Chief Judge*, SENTELLE, and HENDERSON, Circuit Judges.

Opinion for the Court filed by *Chief Judge* MIKVA.

MIKVA, *Chief Judge*: Several home health care providers appeal from a district court decision rejecting their challenges to procedures adopted by the Department of Health and Human Services ("HHS") for the recoupment of Medicare overpayments. Appellants contend that the Secretary of HHS improperly suspended the existing individual claims adjudication process under Part A of the Medicare Act and replaced it with a scheme based on statistical sampling to calculate amounts of overpayment. In granting summary judgment to HHS, the district court held that the statistical method violated neither the terms of the Act nor procedural due process, and that the Health Care Financing Administration ("HCFA") Ruling 86-1 (which purported to explain the Department's legal authority for engaging in sample adjudication) was neither retroactively applied nor subject to notice and comment rulemaking. *See Chaues County Home Health Services,Inc. v. Sullivan*, 732 F. Supp. 188 (D.D.C. 1990). We affirm the district court's decision.

I. BACKGROUND

Appellants are health care providers who receive Medicare payments from HHS for home health services they provide to eligible individuals. The Medicare program is divided into two main parts, one providing insurance for hospital and related post-hospital services (known as "Part A" *see* 42

U.S.C. §§ 1395c-1395i (1988 & 1990 Supp.)), and the other providing additional insurance for supplementary medical services ("Part B," *see* §§1395j-1395w). ("Part C," §§1395x-1395ccc, contains general provisions applicable to both Parts A and B.) The present dispute arises under Part A, which can be further divided into "coverage" determinations and "reasonable cost" determinations. *See Mount Sinai Hospital v. Weinberger*, 517 F.2d 329, *modified*, 522 F.2d 179 (5th Cir. 1975), cert. denied, 425 U.S. 935 (1976). Coverage determinations involve decisions about whether specific items or services are covered by Part A; reasonable cost determinations yield periodic interim payments to providers based on estimated costs incurred and subject to a year-end reconciliation. *See id.* at 335-36.

The present appeals concern only coverage determinations. The payment claims submitted by providers are initially processed by private entities under contract with the Department (called "fiscal intermediaries") on a case-by-case basis to determine (1) whether the amounts are for covered items or services provided to an eligible beneficiary, *see* §1395y(a)(1), and (2) whether, in case a service is not covered, HHS should waive this requirement. Waiver is routine so long as neither the beneficiary nor the provider knew or should have known that the items were not covered. *See* §1395pp(a). For purposes of the waiver determination, the Department presumes good faith by the beneficiary so long as he or she has not previously been notified that a service was not covered, *see* §1395pp(a)(2), and by the provider so long as fewer than 2.5% of its claims were disallowed in the previous quarter. *See* §1395pp(f)(1) & (4) (codifying the regulations in effect at the times relevant to these claims).

HCFA Ruling 86-1, *Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers* (Feb.

20, 1986), describes the Department's policy of allowing fiscal intermediaries to conduct post-payment sampling audits to recoup suspected overpayments. The Secretary concluded that sampling provides the only feasible means for protecting the Medicare Trust Fund in situations where a provider is suspected of overbilling and the number of claims involved is large. *See id.* at 10. HCFA Ruling 86-1 details the type of audit that is appropriate in such circumstances: the fiscal intermediary examines a randomly selected and statistically significant number of sample claims along with their supporting documentation to determine whether they involved noncovered services that the provider knew or should have known were not covered. These results are then extrapolated to the entire universe of claims from that provider for a given time period. The full amount of the provider's overpayment liability is calculated from the percentage of claims denied in the sample. *See id.* at 11. The provider is given the same opportunity to challenge the noncoverage and waiver determinations regarding sample claims as that provided on pre-payment review, and, in case of any incorrect determinations, the overcharge projection will be correspondingly reduced. The provider can also challenge the statistical validity of both the sample and the extrapolation.

In these cases, the Department decided to audit thousands of previously approved payment claims, allegedly after having received a tip that two of the appellants were overbilling, to determine whether there was a pattern of billing Medicare for non-covered services that the providers knew or should have known were not covered. The third appellant was targeted because its claims were so much higher than those of comparable providers. All the claims subject to post-payment review were initially approved, because the services were deemed covered or else waived on the premise that neither the provider nor the beneficiary had reason to know of non-coverage. Claims denied on post-payment review were ones involving non-covered services that HHS decided the

provider (but not the beneficiary) had reason to know were not covered.

The Department engaged in post-payment review of over 1000 claims submitted by and paid to Chaves County Home Health Service, Inc. ("Chaves"), over 2000 claims from Albuquerque Visiting Nurse Services, Inc. ("Albuquerque"), and over 10,000 claims from Bayonne Visiting Nurse Association, Inc. ("Bayonne"). The audit took representative samples of each group of claims (200 each from Chaves and Albuquerque, and 320 from Bayonne), determined that a certain portion of each sample group involved payment for non-covered services that the providers should have known were not covered, and then extrapolated that figure to all claims in assessing repayment liabilities (approximately $47,000 against Chaves, $138,000 against Albuquerque, and over $1.5 million against Bayonne). These figures were reduced after successful appeals regarding denied claims in the sample. The Department withheld payments of subsequent claims to offset the unpaid liabilities. It is about that offset that the providers complain.

II. ANALYSIS

A. Statutory Authority

The primary issue before us is whether Congress has allowed use of a sample auditing procedure for recoupment of overpayments to home health care providers. Nothing in the language or legislative history of the statute specifically authorizes sample audits on post-payment review of coverage determinations, but nothing expressly disallows it either. Appellants primarily rely on the individualized adjudication scheme for initial payment determinations and argue that a sample audit on post-payment review is incompatible with that scheme. By contrast, HHS emphasizes its general power to recoup overpayments and argues that this power

authorizes assessments for overpayments based on extrapolations from a sample audit. Although appellants repeatedly emphasize the small sample size used in these cases (averaging less than 10% of all claims), they never took issue with the statistical validity of the procedure in the proceedings below even though an opportunity for such challenge was made available. We accept the Secretary's reading of the statute as permissible.

According to appellants, nothing in the language of the statute or in its legislative history indicates that Congress authorized HHS to "suspend" individual coverage determinations and rights of appeal when such a procedure is deemed too burdensome. They argue that sample adjudication is incompatible with the statutory scheme requiring case-by-case review of payment claims to decide questions of coverage and waiver. Appellants do not take issue with sample auditing as such, but they assail the extrapolation of those results to the universe of all claims for recoupment purposes (hence the label "sample adjudication"). Appellants emphasize that extrapolation of a sample audit abrogates their right to appeal from specific denials, because they do not know which claims in a group were denied or the exact basis for the denials. The difficulty with their argument is that HHS has not, in fact, suspended individualized determinations and substituted sample adjudication on initial review of payment claims (a decision that would be inconsistent with the statute); instead, the Department has supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review of providers suspected of overbilling. We cannot find a statutory preclusion to such postpayment auditing nor to the method used to accomplish such objective.

In deciding the statutory question, we are of course guided by the principles set out in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984). "If the intent of Congress is clear, that

is the end of the matter, .. . [but] if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843-44; see also *Sulliuan v. Everhart*, 110 S. Ct. 960, 964-66 (1990) (upholding as permissible the Secretary's construction of provisions of the Social Security Act as allowing a net calculation of over- and under-payments of benefits). Although at times appellants seem to be arguing that this is a "*Chevron* step one" case, they are hard pressed to show that Congress spoke to the specific question at issue here; both the statute and legislative history fail to say anything explicit for or against sample adjudication. Appellants ultimately must contend that the Department's interpretation of its authority is unreasonable and not entitled to deference under *Chevron's* second step.

Appellants claim that there is no statutory basis for the Secretary's asserted authority and that, even if there is, other provisions in the Act render unreasonable the Secretary's interpretation of the statute as allowing postpayment sampling audits. We address each contention in turn.

1. *Source of the Secretary's Authority*

The Department does not contend that its sample adjudication scheme for post-payment review of coverage determinations is based on explicit statutory authorization; it relies instead on its general (and uncontested) authority to recoup overpayments from providers. For example, §1395gg(b)(1) explicitly contemplates recoupment of overpayments to providers, declaring that where "more than the correct amount is paid under this subchapter to a provider of services ... and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider," an adjustment shall be made "by decreasing subsequent payments" to the

beneficiary. *See also* 42 C.F.R. § 405.370. Appellants contend that this case is not about whether HHS can recoup overpayments, but rather about how it decides that such overpayments have been made.

As discussed more fully below, sample adjudication has been used in previous instances involving post-payment review of coverage determinations" under Part A. In HCFA Ruling 86-1, the agency simply reiterated its belief that it had the latitude to employ sample audits on postpayment review to efficiently recoup overpayments for non-covered services.

Two courts reviewing post-payment sample adjudications of Part A coverage determinations failed to find any fundamental infirmity in the procedure. For example, in *Mount Sinai Hospital*, the court recounted that

> [a]llegations of wrongdoing by Mount Sinai in operation of the Medicare program were made in 1972. HEW subjected to review by a peer review committee of doctors a sample consisting of 710 patients from a single year. The statistical results of the committee's determinations of medically unnecessary hospital stays and ancillary services drawn from this sample were then applied to all years in question, producing a calculated, as opposed to actual, overpayment figure of $6.3 million.

517 F.2d at 333. Although it did not address the permissibility of sampling as such, the court held that the predecessor of HHS had a common law right of recoupment for overpayments involving services not covered under Part A. *See id.* at 343 ("Under these circumstances and in light of the construction we put on § 1395gg(b) . . ., we think it clear that recoupment has always been available to HEW under facts like those of the instant case."). *See also Daytona Beach General Hosp. v. Weinberger*, 435 F. Supp. 891, 892-93

(M.D. Fla. 1977). More recently, in *Mile High Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988), the court approved sample adjudication under Part B of Medicare.

Although HCFA Ruling 86-1 and the district court both cite Medicare sections that contemplate post-payment adjustments, these provisions deal with "reasonable cost" rather than "coverage" determinations. See 42 U.S.C. §§1395g(a) (authorizing "necessary adjustments on account of previously made overpayments or underpayments"), 1395u(a) (authorizing "such audits of the records of providers of services as may be necessary to assure that proper payments are made under" Part B), 1395x(v)(l)(A)(ii) (dictating that reasonable cost regulations shall "provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive"). Because they govern reasonable cost determinations, we do not read these provisions as explicit statutory authorization for sample adjudication on post-payment review of coverage determinations.

These provisions do, however, demonstrate that the Secretary generally has the duty and power to protect against overpayments to providers. We are not persuaded by appellants' suggestion that congressional silence in Part A should be construed as an intent to restrict postpayment audit procedures. As the court explained in *Mount Sinai Hospital*, "the specific authority for after-the-fact adjustments for payments subsequently found to be erroneous under HEW's reasonable cost regulations does not suggest that other after-the-fact repayments or adjustments were not contemplated." 517 F.2d at 345 (reversing district court's holding that the right to recoup coverage overpayments was abrogated by the comprehensive statutory scheme of the Medicare Act). In

fact, a 1981 amendment to the Act added a provision directing the Secretary to establish utilization guidelines concerning coverage of home health services and "provide for the implementation of such guidelines through a process of selective postpayment coverage review ...." 42 U.S.C. § 1395y(f).

In this case, the district court adopted the holding of another court that had upheld sample adjudication on the basis of these same provisions in the context of Medicare Part B. *See Mile High Therapy Centers*, 735 F. Supp. at 986 ("The above statutory citations give the Secretary considerable discretion and authority to maintain the integrity of the Medicare payment system."); *see also Bowen v. Georgetown Univ. Hosp.*, 109 S. Ct. 468, 472 (1988) (construing §1395x(v)(l)(A)(ii), a subsection governing reasonable cost determinations (quoted above)); *Wilson Clinic & Hosp., Inc. v. Blue Cross of South Carolina*, 494 F.2d 50, 52 (4th Cir. 1974) ("Reopenings are contemplated generally by the Act ... [which] impliedly, if not expressly, envisages the canvassing of all payments to a provider."). The court in *Mile High* concluded that "[t]he statistical sample method is one way of exercising this power" to preserve the integrity of the Medicare trust fund and did not exceed HCFA's statutory authority. *See* 735 F. Supp. at 986. Although Part B is somewhat different from Part A, there is no essential difference in their recoupment powers for coverage overpayments. *See Szekely v. Florida Medical Ass'n*, 517 F.2d 345, 348-49 (5th Cir. 1975), *cert. denied*, 425 U.S. 960 (1976). Furthermore, amendments added in 1986 extended Part A claims adjudication procedures to Part B claims as well. *See* §1395ff (amended by Pub. L. 99-509, § 9341, 100 Stat. 2037 (1986)). (Consequently, a contrary holding on the statutory question in this case could imperil sample adjudication under Part B.)

The logic of sample adjudication, accepted by courts that have approved the technique in other contexts, is that any

minor errors will tend to balance out in the end. As the district court correctly observed:

> The clear majority of those few courts having confronted statistical sampling in analogous contexts, while acknowledging its potential for unfairness in the abstract in particular cases, have nevertheless approved its use, primarily as a logistical imperative but also upon the hypothesis that any arbitrariness evens out in the long run.

Chaves, 732 F. Supp. at 189-90 (footnote omitted). Appellants point to decisions rejecting the Department's use of presumptions to make various determinations under the Social Security Act because these presumptions fail to satisfy the clear requirement for individualized determinations in certain provisions. But presumptions are not the functional equivalent of statistically derived patterns of over-billing by a particular provider. In other contexts and under other statutes, courts have routinely permitted the use of statistical sampling to determine whether there has been a pattern of overpayments spanning a large number of claims where case-by-case review would be too costly. *See, e.g., Illinois Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) (Medicaid); *Michigan Dep't of Edu. v. United States Dep't of Edu.*, 875 F.2d 1196, 1204-06 (6th Cir. 1989) (vocational rehabilitation programs).

In *Illinois Physicians Union*, the court upheld the use of sampling audits to recoup Medicaid overpayments from participating physicians, squarely rejecting the contention that "any formula for sampling and extrapolation is improper per se," and holding that "extrapolation based on review of a relatively small sample is a valid audit technique in cases arising under the Social Security Act." 675 F.2d at 155. *See also State of Georgia v. Califano*, 446 F. Supp. 404, 409-10

(N.D. Ga. 1977) ("Audit on an individual claim-by-claim basis of the many thousands of claims submitted each month by each state [under Medicaid] would be a practical impossibility as well as unnecessary."). Similarly, in Michigan Department of Education the court upheld the government's use of a sample adjudication method to audit over 60,000 individual expenditure authorizations under the Rehabilitation Act. See 875 F.2d at 1205-06 ("[W]hen, as here, the state is given every opportunity to challenge each disallowance as well as the audit technique itself, it appears that the state has been treated as fairly as is practicable under the circumstances.").

HHS concedes, as it must, that these decisions do not settle the statutory question in this case, but the Department contends that these holdings support the reasonableness of the sampling procedure generally, and there is nothing explicit in this statute that would prohibit such a procedure here. Appellants maintain that even if the absence of explicit authorization in the statute is not fatal to the Secretary's procedure, other provisions in the Act render his interpretation unreasonable. As explained below, we agree with HHS that the statutory scheme of individualized review of claims on pre-payment review can be reconciled with a sample adjudication procedure on post-payment review. Such an interpretation is reasonable given the logistical imperatives recognized by courts in other comparable circumstances.

2. *Alleged Incompatibility with the Act*

The process of reviewing initial payment claims requires particularized decisions concerning (1) coverage (was an item or service medically necessary for this person?) and, if not covered, (2) waiver (which is unavailable when the parties knew or should have known that something was not covered). The beneficiary has a right of review for payment

denials based on either of these questions, and the statute specifies that a provider "shall have the same rights that an individual has" for review of Part A denials. *See* §1395pp(d). Much of appellants' statutory argument amounts to a collection of snippets from the Act and its history using the word "individual," though most of the time the term seems to act as a synonym for "person" or "beneficiary" rather than as an antonym for "group" or "class." The real question, however, relates not to the choice of particular words but more generally whether the same rights to individualized factual determinations and an opportunity to challenge specific denials are at stake on post-payment review.

Some of the provisions in the statute cited by appellants for their incompatibility argument, such as putting beneficiaries on notice that their claims were denied (for purposes of imputing knowledge for future waiver determinations), *see* §1395pp, or seeking repayment from a beneficiary when the provider is not available, *see* §1395gg, are simply not implicated in this case. Indeed, both of these provisions inure to the Department's benefit and presumably could be waived by HHS. In any event, all that the statute requires is notification in cases where the providers knew or should have known of non-coverage *and* HHS decides to indemnify the individual beneficiary for any payments they made to the provider. *See* §1395pp(b) ("[T]he Secretary shall notify such individual of the conditions under which indemnification is made ...."). These appeals do not involve indemnification (providers were paid directly for services they rendered tobeneficiaries), and nothing in the Act requires that a provider already deemed to have knowledge of non-coverage be given notice of such a non-coverage determination for purposes of imputing knowledge in the future.

A subsequent amendment to the Act added §1395h(j), which provides in pertinent part that, when a claim for home

health services is denied, the fiscal intermediary shall "furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial ...." Pub. L. 100-203, § 4032, 101 Stat. 133076 (1987) (applicable to claims received on or after January 1, 1988). Though apparently broader than the notice requirements of § 1395pp in effect at the time, the new provisions only cover initial claim denials, *see* §1395h(j)(1), or reconsiderations of such denials, *see* §1395h(j)(2), without ever mentioning reconsiderations of approvals. Furthermore, section 1395pp(a), which required notification of both the provider and beneficiary in cases where non-coverage was waived, only applies when neither party was already on notice and therefore would not be relevant in cases such as these where the provider is later deemed to have had the requisite knowledge of non-coverage.

Nor are the providers' rights to seek reimbursement from beneficiaries implicated in these cases. The legislative history accompanying §1395pp recognized that in cases where the beneficiary knew or should have known of non-coverage, "liability would remain with the beneficiary and the provider could ... exercise his rights under State law to collect for the services furnished ...." S. REP. No. 1230, 92d Cong., 2d Sess. 294 (1972). For purposes of the original claims approvals here, the beneficiaries were deemed to be without knowledge of any non-coverage. The revised waiver determinations on post-payment review only applied to the providers. *See* HCFA Ruling 86-1, at 8-9. Under these circumstances, a provider would have no right to seek reimbursement for subsequently denied claims from the beneficiary unless the provider could show that the beneficiary (including any outside the sample) was previously informed that he was receiving noncovered services. *See id.* Furthermore, even if the provider could show that the beneficiaries of payment claims denied without review also had the requisite knowledge (notwithstanding the provider's implicit representation that such knowledge was

lacking when the claim was initially submitted), providers are constrained in their ability to charge patients for services subsequently deemed to be non-covered. *See* §1395cc(a)(1)(B) (providers must agree not to seek reimbursement from patients for services that HHS decides are not covered more than three years after original notice of payment, and the Secretary may reduce this statute of limitations to one year if circumstances warrant).

Appellants also contend that sample adjudication vitiates their rights to appeal. Unlike the notice requirements discussed above, the statute makes no apparent distinction between pre-payment and post-payment review when setting out an individual's right to appeal an adverse determination. A beneficiary's right to appeal extends to "any determination" with which an individual is dissatisfied. *See* 42 U.S.C. §1395ff(b). As noted previously, §1395pp(d) accords providers the same rights as individuals. The issue, then, is whether the right to appeal initial claim denials is fully transferable to denials on postpayment review, or whether a right to dispute denials in the sample and challenge the statistical validity of the extrapolation suffices to protect the interests of providers. Appellants fill in this crucial gap in their position by relying on a supposed concession by HHS that, in appellants' words, a provider's "rights are the same whether the claim is being adjudicated at the time it is submitted or upon post-payment review." However, HHS made no such concession, noting only that its sample adjudication procedure afforded providers the same protections and right to challenge denials in the sample group, not that the rights were equally applicable to all post-payment denials. Nothing in the statute appears to require case-by-case review of all claims on post-payment review. At best, congressional intent on the matter is ambiguous.

The question is what "determination" was made in these cases that could be subject to appeal. As HCFA explained in its ruling, "[s]ampling only creates a presumption of validity

as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step." Ruling 86-1, at 11. A provider might first of all object to a coverage or waiver determination as to a claim in the sample, and HCFA's sample adjudication scheme permitted such challenges. In fact, the providers in these cases were able to successfully challenge many of the denied sample claims, thereby reducing their projected overpayment liability. Secondly, a provider may also take issue with the statistical validity of an extrapolation from the sample, and this right was also available in the proceedings below. Although they repeatedly emphasize that the sample sizes were too small, appellants failed to make any such objections to the statistical validity of the extrapolation in the proceedings below. Instead, the providers argued that the entire scheme is unauthorized because their right to appeal specific claim denials has been foreclosed.

Sample adjudication is not, however, a determination that some particular, though unidentified claims outside the sample should have been denied; instead, it is a monetized estimate of the scope of a provider's overcharges derived from a sample. To the extent that appellants were dissatisfied with *that* adverse determination, they were given an ample opportunity to challenge its basis. This is not to say that the providers were prohibited from raising challenges based on particular claims in the non-sample universe. For instance, as explained previously, a provider is permitted to identify individual beneficiaries of claims not in the sample who were on notice that the claims involved non-covered services and to then directly bill those beneficiaries. Furthermore, in an effort to challenge the accuracy of the extrapolation, a provider could separately present evidence of a different random sample from the universe of claims that yields a lower rate of denials or prove that the projection is not a true estimate of the rate of denials in the non-sample universe.

For instance, if a sampling projection estimated 100% denials in the non-sample universe, a provider could demonstrate that one or more of those unreviewed claims was proper.

Even when a provider is not able to invalidate the statistical validity of the sample audit, if the extrapolation has improperly invalidated any number of correct claims the provider could always appeal the determination by establishing the validity of all or a sufficient number of its actual claims to demonstrate that the HHS projection is factually impossible of correctness. Obviously, where thousands of claims are involved, this would impose a daunting burden on the provider, but the alternative urged by appellants imposes an equally daunting burden on the agency. It is not apparent to us that the regulatory scheme becomes invalid simply because it requires the protesting provider rather than the agency to bear the burden.

Appellants also claim that the Department's interpretation of the statute is not entitled to deference because it conflicts with HHS regulations,and policy statements. They contend that the regulations implementing Part A, *see* 42 C.F.R. §§ 405.701-.750 (1989), clearly require individual factual determinations and administrative review in making coverage denials. When initial determinations of non-coverage and no waiver are made on payment claims, the provider is entitled to written notice "stat[ing] in detail the basis for the determination." 42 C.F.R. § 405.702. At the request of an aggrieved party, initial payment denials can be reconsidered (§ 405.710), and providers are entitled to the same procedural rights on reconsideration, including a written statement (§ 405.716) and administrative review (§405.720). Again, to the extent that the regulations and other agency pronouncements reiterate the requirement for case-by-case review at the initial payment stage, they do not address the question of post-payment sample audits for recouping overpayments.

HHS emphasizes that sample adjudication is a longstanding practice, utilized at least since 1972. Indeed, internal manuals clearly contemplate just such a procedure. For example, the *Medicare Intermediaries Manual*, brought to the district court's attention by the plaintiffs, provides that

> [tlhe decision to conduct a sample study of a provider's claims constitutes a reopening of all determinations .... Send a notice to the provider as soon as possible explaining: the reason for the study (*e.g.*, possible over-utilization of services); the period to which the results will apply; the sampling procedure, including the method used to select the sample and a statement that the sample findings will be projected to the entire population of claims.

Medicare Intermediaries Manual, § 3799.5. Furthermore, the regulations governing the collection and compromise of claims for over-payments against providers appear to draw a distinction between pre-payment and postpayment review in defining the scope of the right to appeal. *See* 42 C.F.R. § 405.374(j) ("Any action taken by HCFA under this section regarding the compromise of an overpayment claim ... is not an initial determination for purposes of the appeal procedures" under, *inter alia*, 42 C.F.R § § 405.702-.730.) . Appellants are thus unable to demonstrate that the sample adjudication procedure used in these cases was incompatible with either the statute or Department regulations. Thus, we cannot say that the Secretary's interpretation of his authority under the Act is unreasonable.

B. *Procedural Due Process*

Appellants contend that they enjoy a clear property interest in retaining previously made payments for services rendered and are therefore entitled to the protections of due process.

To sustain such a contention they have a very difficult burden of persuasion in light of the three-factor analysis adopted in *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). Absent an explicit provision in the statute that requires individualized claims adjudications for overpayment assessments against providers, the private interest at stake is easily outweighed by the government interest in minimizing administrative burdens; in light of the fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates. *See Illinois Physicians Union*, 675 F.2d at 157 ("[I]n view of the enormous logistical problems of Medicaid enforcement, statistical sampling is the only feasible method available."). It should be remembered that appellants failed in these cases to timely and specifically challenge the statistical validity of the sampling procedure as applied to them. HHS emphasizes that providers have no legitimate expectation of retaining payments for services they knew or should have known were not covered, that subjecting the audit to notice and hearing minimizes the risk of error, and that the cost of case-by-case review would exceed the amounts of overpayment. We can find no general constitutional defect with sample adjudication.

C. *Irregularities in Adoption of HCFA Ruling 86-1*

1. *Retroactive effect*

Appellants urge that their challenges before the agency to the sample auditing procedure were rejected on the strength of HCFA Ruling 86-1 even though that ruling was issued after their overpayment assessments were made. If Ruling 86-1 changed HHS procedures, then its use here indeed would be impermissibly retroactive. *See Bowen v. Georgetown Univ. Hosp.*, 109 S. Ct. 468, 471-74 (1988). However, the Ruling was not the source of administrative authority in these cases but merely explained and reaffirmed the Department's

long-standing and well-established practice of conducting sample audits. While the past frequency of such audits is unclear, the practice appears to have been in use as early as 1972. *See Mount Sinai Hosp.*, 517 F.2d at 333; *Daytona Beach General Hosp.*, 435 F. Supp. at 892-93. The audits at issue in *Mile High Therapy Centers*, 735 F. Supp. at 985, were undertaken in the early 1980s, and the sample audits in the cases before us on appeal also predated HCFA Ruling 86-1. Moreover, sample auditing is referenced in internal agency manuals. *See Medicare Intermediaries Manual*, § 3799.5 (quoted above); *Medicare Carrier's Manual* § 7150 (discussed in *Mile High*, 735 F. Supp. at 985-86). In light of this evidence that sample adjudication represents a long-standing HHS procedure, we reject appellants' retroactivity objection.

2. *Compliance with APA Rulemaking Procedures*

Appellants finally contend that HCFA Ruling 86-1 was adopted without the notice and comment procedures required by the Administrative Procedure Act (APA). *See* 5 U.S.C. § 553 (1988). The sole question is whether Ruling 86-1 is excepted from the APA requirements as an interpretive rule. *See* § 553(b)(A); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-47 (D.C. Cir. 1987). Appellants argue that HCFA Ruling 86-1 is a legislative rule, and not just an advisory statement, because it is binding both by its own terms and as used by the Department in the proceedings below. The Department responds that it has been performing sample audits for nearly two decades and that HCFA Ruling 86-1 simply states what the agency thinks it can do under the statute and reminds parties of their existing duties. *See Mile High*, 735 F. Supp. at 985-86 (holding that HCFA Ruling 86-1 is an interpretive rule not subject to notice and comment rulemaking requirements); *cf. McCown v. HHS*, 796 F.2d 151, 157 (6th Cir. 1986) (policy statement concerning offset policies for social security disability benefits was

interpretive), *cert. denied,* 479 U.S. 1037 (1987). The dispute, therefore, boils down to the previously-resolved question of whether sample adjudication for Part A overpayments was a longstanding practice or a brand new scheme ushered in by HCFA Ruling 86-1. As explained above, we agree that it was the former.

III. CONCLUSION

Appellants' remaining challenges to the proceedings below are equally without merit. The statutory question is complicated, but this much is clear: neither the plain language nor the legislative history discusses sample adjudication. Appellants' claim that HHS is proposing an unreasonable interpretation of its authority under the statute is close, but not strong enough to trump the deference we must accord agency interpretations of an ambiguous governing statute under *Chevron.* Sample adjudication represents a judicially approved procedure that can be reconciled with existing Medicare requirements for case-by-case consideration on pre-payment review of claims. The district court's order granting summary judgment to the Secretary of HHS is

Affirmed.

APPENDIX B

UNITED STATES COURT OF APPEALS

For the District of Columbia Circuit

No. 90-5100 **September Term**, 1990
USDC Civ. No. 86-2691

Chaves County Home Health Service Inc., et al.,
Appellants

FILED: JUL 26 1991
CONSTANCE L. DUPRE
CLERK

v.

Louis W. Sullivan, M.D., Secretary of the Department of Health and Human Services, et al.,
Appellees

Before: MIKVA, Chief Judge; SENTELLE and HENDERSON, Circuit Judges

ORDER

Upon consideration of appellants' Petition for Rehearing and of the response thereto, it is

ORDERED, by the Court, that the petition is denied.

Per Curiam:
FOR THE COURT:
CONSTANCE L. DUPRE, CLERK
By: Robert A. Bonner,
Deputy Clerk

APPENDIX C

SECTION 1815(a), 1842(a), and 1861(v)(1)(A)(ii) (42 U.S.C. 1395g(a), 1395u(a), and 1395x(v)(1)(A)(ii)). -- HOSPITAL INSURANCE AND SUPPLEMENTARY MEDICAL INSURANCE--USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO PROVIDERS AND SUPPLIERS

HCFAR-86-1

HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible.

The provider billed and was paid by Medicare for services to beneficiaries from September 1982 through July 1985. As a result of a subsequent audit of the provider's Medicare claims, the intermediary discovered a large number of bills for medically unnecessary services. The intermediary also determined that the provider knew or should have known that the services were not covered and, therefore, was not entitled to have payment made to it for the services.

The intermediary considered conducting a case-by-case review in order to determine the amount the provider had been overpaid for the services. This would have entailed an examination of all of the provider's beneficiary records for the period in question in order to identify those beneficiaries who had received unnecessary services. It also would have been necessary to tabulate the total amount that Medicare had paid the provider for each beneficiary. The intermediary decided that this method of determining the amount of the overpayment was not administratively feasible, given the volume of records involved and the cost

of retrieving and reviewing all the beneficiary records for the period in question. The cost of identifying and calculating each individual overpayment itself would constitute a substantial portion of the amount the intermediary might reasonably be expected to recover. Further, the allocation of sufficient staff to reexamine all individual claims for the period in question would interfere with current claims processing activities to an unacceptable degree.

The intermediary notified the provider that, because of the volume of records and the costs of retrieving and reviewing all records for the period as discussed above, it intended to project the overpayment by reviewing a statistically valid sample of beneficiary records and that if it were determined that the provider had been overpaid for the sample cases, it would project the results (again using statistically valid methods) to the entire population of cases from which the sample had been drawn. This would result in a statistically accurate estimate of the total amount the provider had been overpaid for services to these beneficiaries.

The provider objected to the intermediary's use of sampling to project the overpayment on the following grounds:

There is no legal authority in the Medicare statute or regulations for HCFA or its intermediaries to determine overpayments by projecting the findings of a sample of specific claims onto a universe of unspecified beneficiaries and claims.

Section 1879 of the Social Security Act, 42 U.S.C. 1395pp, contemplates that medical necessity and custodial care coverage determinations will be made only by means of a case-by-case review.

When sampling is used, providers are not able to bill individual beneficiaries not in the sample group for the services determined to be noncovered.

Use of a sampling procedure violates the rights of providers to appeal adverse determinations.

The use of sampling and extrapolation to determine overpayments deprives the provider of due process. (The succeeding presentation of our decision and supporting facts is applicable also to the use of sampling to project overpayments to suppliers (including physicians) whose claims are processed by Medicare carriers when 100 percent readjudication would be excessively costly or impractical.)

The Supreme Court has long recognized that the Federal Government possesses an inherent right to recover monies illegally or erroneously paid out. United States v. Carr , 132 U. S. 644, 650 (1890); Wisconsin Cent. R. R. v. United States, 164 U.S. 190, 212 (1986). This right exists independent of statute. See United States v. Wurts , 303 U.S. 414, 416 (1938); Grand Trunk W. Ry. v. United States, 252 U.S. 112, 121 (1920). The Government may enforce its right of recoupment by reasonable means, and it may exercise that right without resorting to litigation by offsetting the amount against sums otherwise due. United States v. Munsey Trust Co., 332 U.S. 234, 239-240 (1947). Offsets against current or subsequent obligations may be used to prevent a recipient of Federal funds from retaining monies that are later found to have been unauthorized by the terms and conditions under which they were received. Wisconsin Cent. R.R. v. United States, supra, 164 U.S. at 211-212.

The Government's common law right of recoupment, and its corollary power of recovery by offset, are based on strong considerations of public policy. All funds at the disposal of the Government belong to the public. As custodian of these funds, a Federal agency has the fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. Accordingly, if the public's money has been expended in a manner not authorized by statute, the agency's obligation requires it to take administrative actions necessary to prevent an unjust

enrichment by the recipient at the expense of the Federal treasury. See United States v. Wurts, supra, 303 U.S. at 415-416; Grant Trunk W. Ry. v. United States, supra, 252 U.S. 120-121.

The common law right to recover Federal funds has been specifically recognized as being fully applicable to the Medicare program. Mt. Sinai Hospital v. Weinberger, 517 F.2d 329 (5th Cir. 1975); Wilson Clinic and Hospital, Inc. v. Blue Cross, 494 F.2d 50 (4th Cir. 1974). Moreover, the courts have also recognized that extrapolation based on a sample is a valid audit technique in cases arising under the Social Security Act. Illinois Physician Union v. Miller , 675 F.2d 151 (7th Cir. 1982); State of Georgia v. Califano, 446 F.Supp. 404 (N.D. Ga. 1977); New Jersey Welfare Rights Organization v. Cahill , 349 F.Supp. 501 (D.N.J. 1972); Rosado v. Wyman , 322 F.Supp. 1173 (E.D. N.Y. 1970), aff'd 402 U.S. 991 (1971). In view of the enormous logistical problems in determining massive overpayments in social welfare programs, sampling is the only feasible method available. State of Georgia v. Califano, supra; Illinois Physicians Union v. Miller, supra.

Congress has affirmed the Government's right to recover Medicare Trust Funds by reasonable means from those who have no right to retain them. Section 1815(a) of the Social Security Act, 42 U.S.C. 1395g(a), authorizes "necessary adjustments on account of previously made overpayments or underpayments" under Medicare Part A. Similarly, as to Part B of Medicare, section 1842(a), 42 U.S.C. 1395u(a), provides that carriers make determinations as to the amount of payments to be made to providers of services and other persons, and authorizes such audits of the records as may be necessary to assure that proper payments are made. In addition, section 1861(v)(1)(A)(ii) of the Act, 42 U.S.C. 1395x(v)(1)(A)(ii), provides for the "making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate

reimbursement produced by the methods of determining costs proves to be either inadequate or excessive." These statutory requirements, in effect, would be abrogated if sampling were not available to determine Medicare overpayments. The imposition of such a result would be inconsistent with the settled principle that, when Congress creates a statutory right, the existence of appropriate remedies to enforce that right will be presumed in the absence of a clar indication of a contrary congressional intent. Texas & N.O.R.R. v. Brotherhood of Railway & Steamship Clerks, 281 U.S. 548, 569-570 (1939); Sullivan v. Little Hunting Park, Inc., 396 U.S. 229, 239 (1969).

Since HCFA's contractors process vast numbers of Medicare claims (for example, in fiscal year 1985, intermediaries received over 59.5 million Medicare claims and carriers received over 270.8 million Medicare claims), an interpretation that title XVIII of the Act mandates that a 100 percent review of cases be conducted before HCFA or its contractors can determine that providers or suppliers have been overpaid would make it virtually impossible for HCFA to implement these statutory provisions in many cases. A case-by-case review could require a significant diversion of staff from the ongoing claims process, and the cost of determining the amount of an overpayment would be prohibitively high unless a sampling method were used. To fulfill the congressional intent, HCFA must adopt realistic and practical auditing procedures. The alternative is to conclude that the intent of Congress was that, if case-by-case overpayment determinations are not administratively feasible, the Medicare Trust Funds must forego restitution of funds improperly obtained by providers and suppliers. We do not believe that was Congress' intent.

We also do not believe that the statutory provisions limiting provider or beneficiary liability preclude the use of sampling. In instances where Medicare coverage is denied because of items or services furnished are not "medically necessary" or constitute "custodial" care, section 1879 of the Act, U.S.C. 1395pp (42 CFR 405.330), authorizes

a limitation of the beneficiary's liability when the beneficiary did not know, and could not reasonably be expected to have known, that the items or services were not "medically necessary" or that they constituted "custodial" care. The Medicare program will make payments to the provider when both the beneficiary and the provider were without the requisite knowledge. When the beneficiary did not have such knowledge, but the provider did, liability for the denied services rests with the provider and the beneficiary's liability is waived. The beneficiary will be indemnified by the Medicare program if he or she has already paid the provider. See 42 U.S.C. 1395pp. Liability will rest with the beneficiary only when he or she knew or could have been expected to know that the items or services furnished were not "medically necessary" or were "custodial" in nature.

The use of sampling to determine overpayments for medically unnecessary services or custodial care does not deprive a provider of its right to bill those beneficiaries who knew or should have known that they were receiving these services. Under the governing regulation, 42 CFR 405.334, a beneficiary is presumed not to have had such knowledge unless he or she was notified in writing by the provider, the intermediary, or the Peer Review Organization (PRO). For example, when a beneficiary who is receiving a course of treatment has received a previous denial notice stating that similar items or services were not covered, the previous denial notice would constitute evidence that the beneficiary did or should have had knowledge of noncoverage. See 42 CFR 405.334 for examples of acceptable written notice to the beneficiary. The operation of this provision effectively serves to resolve most limitation of liability questions in the beneficiary's favor. However, a provider that wishes to bill individual beneficiaries not included in the sample can identify whose individuals who were previously informed that they were

receiving noncovered services by inquiring of the intermediary or PRO as to whether it sent a notice to the individual. (The provider presumably did not give notice to the beneficiary that the services were not covered because, if it had, it is unlikely that it would have billed Medicare for the services.)

Even if we assume that a provider is effectively precluded from billing a beneficiary in certain cases, this assumption would not bar the Government from its fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. As between the provider and the Government, strong considerations of public policy favor recovery. On the other hand, the provider had the responsibility to know and should have known that the services furnished were not medically necessary. Moreover, as the United States Court of Appeals for the Fifth Circuit recognized in Mt. Sinai Hospital of Greater Miami v. Weinberger, 517 F.2d 329 (5th Cir. 1976), the provider assumes substantial responsibility for overpayments.

. . . [the hospital] is not a neutral, innocent party in this three-way transaction between HEW, Medicare beneficiary and Medicare provider. The decision to provide a service is made by the individual attending physician, who is far better informed on both the medial issue and the scope of Medicare coverage than is the patient-beneficiary. The physician is either an employee of the hospital or a doctor with staff privileges. Whatever else the granting of staff privileges may connote, it is clear to us that it involves a delegation by the hospital of authority to make decisions on utilization of its facilities. 534 F.2d at 338.

In reimbursing providers, HCFA has to balance the need to process billings rapidly in order that a provider's liquidity needs do not suffer and the need to verify that the claims submitted are for services covered by the Act. Mixed into this balance is the volume of claims which must be

reviewed. Considering the volume of claims (as cited earlier to be over 330.3 million for fiscal year 1985), it is virtually impossible to examine each bill submitted by a provider or supplier in sufficient detail to assure before payment in every case that only medically necessary services have been provided. Therefore, as a practical matter, HCFA and its contractors must

depend on the provider to submit claims for services that are covered by the Act. In most cases, this reliance is justified. However, if HCFA or its contractors later have reason to make an indepth and careful review of claims for services which had been previously paid and discover that medically unnecessary services have been provided, a provider cannot cry "foul" when these payments (to which they were never legally entitled) are recovered.

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

The provisions of the statutes and regulations provide a constitutionally sufficient means by which the provider may challenge an overpayment determination. In cases of denials made through sampling which are based on

medical necessity or custodial care, section 1879 of the Act, 42 U.S.C. 1395pp, permits the provider to assert the same appeal rights that an individual has under the statute when the individual does not exercise his rights to appeal. Under Part A, these rights include an opportunity for reconsideration (42 CFR 405.710-504.716), an oral evidentiary hearing by an administrative law judge (42 CFR 405.720-405.722), Appeals Council Review (42 CFR 405.701(c) and 405.724), and finally judicial review if the amount in controversy is $1,000 or more (42 CFR 405.730; 42 U.S.C. 1395ff(b)(2)). In cases which do not involve medical necessity or custodial care, 42 CFR 405.370, et seq. sets out the applicable procedures through which current payments may be suspended (offset) to recover an overpayment under the Medicare program. Under 42 CFR 405.371, a provider is given notice as to the basis for the overpayment and an opportunity to respond before an intermediary may suspend current Medicare reimbursement. 42 CFR 405.372, in conjunction with 42 CFR 405.370(b), forestalls any suspension pending consideration of any statement by the provider in opposition to the notice of suspension. Finally, if it is determined that a suspension should go into effect, written notice of the determined will be sent to the provider or other supplier. The notice will contain specific findings on the conditions upon which the suspension was based and an explanatory statement for the final decision. Thus, the administrative scheme provides sufficient means for a provider to challenge overpayment determinations that are made on the basis of sampling.

Under Part B, suppliers who accept assignment may request a Medicare carrier to review a payment determination with which the supplier disagrees (42 CFR 405.807). If the supplier is dissatisfied with the carrier's review determination, the supplier may request a hearing before a carrier hearing officer if the amount in controversy is $100 or more (42 CFR 405.820). There are no further appeals

available under Part B. In U.S. v. Erika, Inc., 456 U.S. 201 (1982), the Supreme Court ruled unanimously that, under current law, the Part B hearing is rightfully the final step in the Part B appeals process.

In summary, the use of sampling is a reasonable and cost effective method of projecting overpayments under Medicare. It is not unfair to a provider or supplier to hold it accountable for the receipt of Medicare funds to which it is not entitled under the statute. To the contrary, allowing a provider or supplier improperly to retain large sums of program funds would be unfair to the intended beneficiaries of Medicare and to the taxpayers who contribute to the trust funds. As the Supreme Court held in Richardson v. Perales, 402 U.S. 389 (1971), the system must not only be fair, but it must work.

Accordingly, it is held that the use of statistical sampling to project an overpayment is consistent with the Government's common law right to recover repayments, the Medicare statute, and the Department's regulations, and does not deny a provider or supplier due process. Neither the statute nor regulations require that a case-by-case review be conducted in order to determine that a provider or supplier has been overpaid and to determine the amount of overpayment.

DATED: 2/20/86

Henry R. Desmarais

Acting Administrator, Health Care
Financing Administration

(2)

No. 91-674

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

Chaves County Home Health Services, Inc., et al.,
Petitioners

v.

Louis W. Sullivan, M.D., Secretary,
Department of Health and Human Services,
Respondent

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

SUPPLEMENTAL APPENDIX

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHAVES COUNTY HOME HEALTH
HEALTH SERVICES, INC., et al..

v.

CIVIL ACTION
NO. 86-2691 (TPJ)
FILED: FEBRUARY 12, 1990

LOUIS W. SULLIVAN,
SECRETARY, DEPARTMENT
OF HEALTH AND HUMAN
SERVICES

MEMORANDUM AND ORDER

Plaintiffs are home health care providers who render medical and related services to Medicare-eligible patients pursuant to agreements with defendant U. S. Department of Health and Human Services ("HHS"). HHS then pays them the reasonable cost of such of those services as are covered by the Medicare Act, 42 U.S.C. §§1395 *et seq.* ("the Act"). [1]

Plaintiff's claims for their services are processed and paid initially by a fiscal intermediary (usually an insurance carrier), but plaintiffs are (as are all such providers) liable to the government for reimbursement of

[1] The services not covered by the Act are those "which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury" or are for "custodial care." 42 U.S.C. § 1395y.

payments later found by the intermediary or HHS on post-payment review to have been made for non-covered services. See, generally, *Mount Sinai Hospital v. Weinberger*, 517 F.2d 329, 338 (5th Cir.) *reh'g denied en banc with opinion*, 522 F.2d 179 (5th Cir. 1975)(holding that provider may look to patient as source of payment), *cert. denied*, 425 U.S. 935 (1976).

In this case, HHS made redeterminations with respect to 1,261 claims submitted by and paid to plaintiff Chaves County Home Health Services, Inc. ("Chaves County"), 2,460 paid claims of plaintiff Albuquerque Visiting Nurse Services, Inc., ("Albuquerque VNS") and 10,791 paid claims submitted by plaintiff Bayonne Visiting Nurse Association, Inc. ("Bayonne VNA"). It did so, however, relying entirely upon a review of ostensibly representative samples of 200 claims in the case of Chaves County, 200 claims in the Albuquerque VNS case, and 320 claims in the Bayonne VNA case. Having determined that a certain proportion of each sample reflected payments for non-covered services , HHS demanded repayment of $46,900 from Chaves County, $138,100 from Albuquerque VNS, and $1.5 million from Bayonne VNA. When the repayments were not forthcoming, HHS withheld reimbursement to plaintiffs on subsequent claims by way of offset.

Plaintiffs allege that the use of the statistical sampling method to calculate amounts of overpayment, by which a fraction of the claims submitted by a particular provider is reviewed, and the result projected to the universe of the whole without individual review of each claim, is illegal. They contend that the method operates to deny them due process under the Fifth Amendment; that

it is contrary to the terms of the Medicare Act; and that it implements a governmental policy which is not only arbitrary and capricious, but was adopted without the notice-and-comment formalities made obligatory in the case of certain agency rule-makings by the Administrative Procedure Act, 5 U.S.C. §553 ("APA").

HHS responds by defending the legality and the mathematical validity of the sampling method, insisting that the logistical impossibility of affording an individual review to every Medicare claim submitted justifies its use as a matter of manifest necessity. It also contends that the Court is without jurisdiction to entertain the case, because the plaintiffs have not fully exhausted all possibilities of administrative relief within HHS. [2]

The case is now before the Court on defendant's motion to dismiss or for summary judgment and plaintiffs' cross-motion for summary judgment. Although the case has been fully --indeed, fulsomely-- briefed and argued for many months, the Court has delayed decision in hopes that further guidance might be forthcoming from the U.S. Supreme Court or a circuit court of appeals. No such guidance has materialized, however, and it is necessary that the case be decided now on the basis of such scant authority as is extant.

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[2] The Court concludes that it has subject matter jurisdiction under 42 U.S.C. §405(g). See *Bowen v. City of New York*, 476 U.S. 467 (1986). The validity *vel non* of statistical sampling has been pursued administratively by plaintiff Chaves County to the Appeals Council level within HHS, and the Appeals Council has declined to entertain the issue.

The clear majority of those few courts having confronted statistical sampling in analogous contexts, while acknowledging its potential for unfairness in the abstract in particular cases, have nevertheless approved its use, primarily as a logistical imperative but also upon the hypotheses that any arbitrariness evens out in the long run. [3] In what appears to be the only federal appellate case on the subject, the Seventh Circuit upheld statistical sampling in *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982), as a means to audit physicians receiving reimbursement for medical services provided under the Medicaid program. The court first considered whether the results of its use were arbitrary:

> We find nothing in this procedure, however, to suggest that extrapolation inherently works to the detriment of the physician. Sampling and extrapolation is no more likely to result in a situation where the physician will be required to return monies when there has been no overpayment than in a situation where the Department will not recoup the full amount overpaid. The audit procedures are not arbitrary, capricious or invidiously discriminatory. *Id.* at 156.

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[3] The only case known to the Court to have disallowed a sample-based overpayment determination is *Daytona Beach General Hospital, Inc. v. Weinberger*, 435 F. Supp. 891 (M.D. Fla. 1977), in which the court took exception to the size of the sample used, but did not categorically reject sampling as a review technique. The court did hold, however, that the extrapolation of the sample results to the entire claims universe constituted a due process violation.

The court then went on to consider the physicians' due process argument:

> There is no merit to [appellant's] contention that the Department procedures do not comport with due process. The process due varies with the circumstances and various factors must be considered when evaluating administrative procedures. These factors are: (1) the private interest affected by the official action; (2) the risk of an erroneous deprivation of that interest; and (3) the governmental interest, including the function involved and the fiscal and administrative burdens that other procedures would entail.
>
> We agree with [appellant] that she had a substantial interest in receiving her full statutorily allotted compensation for services actually rendered. However, in balancing the interests of the parties, the balance is heavily weighed in favor of the Department. The Department processes an enormous number of claims and must adopt realistic and practical auditing procedures. We agree with the district court's conclusion that, in view of the enormous logistical problems of Medicaid enforcement, statistical sampling is the only feasible method available. *Id.* at 157 (citations omitted).

Several district courts have accepted statistical sampling as an appropriate auditing technique for settling accounts between the government and a private sector care provider under both Medicaid and other social welfare programs. In *Georgia v. Califano*, 446 F. Supp. 404

(N.D. Ga. 1977), a Medicaid case, the court held that "[p]rojection of the nature of a large population through review of a relatively small number of its components has been recognized as a valid audit technique and approved by federal courts in cases arising under Title IV of the Social Security Act. " *Id.* at 409. It also pointed out that "mathematical and statistical methods are well recognized as reliable and acceptable evidence in determining adjudicative facts." *Id.* See also *Rosado v. Wyman*, 322 F. Supp. 1173 (E.D.N.Y.), *aff'd*, 437 F.2d 619 (2d Cir. 1970), *aff'd* 402 U.S. 991 (1971); *New Jersey Welfare Rights Organization v. Cahill*, 349 F. Supp. 501 (D. N.J. 1972) (AFDC), *aff'd*, 483 F.2d 723 (3d Cir. 1973).

Both the *Illinois Physicians Union* and the *State of Georgia* cases were relied upon by yet another district court in *United States v. DeCosmo*, Civil No. 82-631, slip. op. (M.D. Fla. Feb. 17, 1984), in a Medicare case. The court found that sampling is "the only practical method" of auditing claims "since a physician may submit literally thousands of claims during the calendar year," *id.* at 10, and concluded that statistical sampling may properly be used to determine the existence and amount of overpayments under the Act. *Id.* at 11.

The most recent case, arising in a Medicare Part B context, appears to be *Mile High Therapy Centers, Inc. v. Bowen*, No. 86-F-1853, slip op. (D. Colo. May 27, 1988), which held that the use of statistical sampling to determine overpayments of Medicare reimbursement, in circumstances where case-by-case review is not administratively feasible, is within the statutory authority of HHS. The court said:

> In adopting this method, the agency relied on its authority to use any reasonable means to recover overpayments . . . 42 U.S.C. §1395g(a) authorizes "necessary adjustments on account of previously made overpayments or underpayments." 42 U.S.C. §1395u(a) gives the Secretary authority to make determinations of the rates and amounts of payments to be made for services and conduct audits to insure proper payments are made. 42 U.S.C. §1395x(v)(1)(A)(ii) provides for retroactive corrective adjustments in payments when the cost proves inadequate or excessive.
>
> A reasonable interpretation of the statute by the administrator of an agency is entitled to considerable weight. . . . The above statutory citations give the Secretary considerable discretion and authority to maintain the integrity of the Medicare payment system. The statistical sample method is one way of exercising this power. The agency's policy does not exceed their statutory authority. *Id.* at 4 (citations omitted).

Plaintiffs also argue that the HHS' ruling explaining the use of the statistical sampling method (known as HCFA Ruling 86-1 of February 20, 1986) is the sort of "substantive rule" contemplated by 5 U.S.C. §552(a)(1)(D) of the APA as requiring notice-and-comment rulemaking formalities. Defendant responds that HCFA Ruling 86-1 is merely an "interpretive rule," which is not subject to formal rulemaking requirements. *See* 5 U.S.C. §553(b)(3)(A).

The *Mile High Therapy Center* court again agreed with HHS and held that its various directives counselling

upon use of the sampling technique were exempt from the notice-and-comment requirements of the APA, because they represented only an "interpretive rule." The court said:

> The *Medical Carrier's Manual* and the HCFA ruling explaining the statistical sample method are merely interpretations of an existing statute. They do not create new law or depart from prior practice. Agency manuals, guidelines and memoranda are interpretive rules not subject to the APA. . . . Defendants did not violate the APA in using the Manual as a means of calculating overpayments. *Id.* at 3 (citations and footnote omitted).

Thus, each of plaintiffs' contentions here, it appears, have been addressed and rejected by at least one other court. This Court has been shown no reason to believe that those courts were any of them less wise or well-informed, and, in the aggregate, the judicial authority presently available overwhelmingly supports the proposition that statistical sampling in the readjudication of Medicare claims by HHS to determine overpayments and reimbursement liability is lawful.

It is, therefore,

ORDERED, that plaintiff's motion for summary judgment is denied; and it is

FURTHER ORDERED, that defendant's motion for summary judgment is granted, and the complaint is dismissed with prejudice.

No. 91-674

In the Supreme Court of the United States

OCTOBER TERM, 1991

CHAVES COUNTY HOME HEALTH SERVICE, INC., ET AL., PETITIONERS

v.

LOUIS W. SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the use of statistical sampling by the Secretary of Health and Human Services, in the exercise of his undisputed power to recoup Medicare overpayments and conduct post-payment audits of health care providers, violates the Medicare Act, Social Security Act, Title XVIII, 42 U.S.C. 1395 *et seq.*

2. Whether Health Care Financing Administration Ruling 86-1, which reaffirmed the legality of the agency's practice of using statistical sampling as a technique for recouping Medicare overpayments, is a substantive and retroactive rule subject to notice and comment rulemaking under the Administrative Procedure Act.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-21a) is reported at 931 F.2d 914. The opinion of the district court (Supp. App. 1-8) is reported at 732 F. Supp. 188.

JURISDICTION

The judgment of the court of appeals was entered on April 26, 1991. A petition for rehearing was denied on July 26, 1991. The petition for a writ of certiorari was filed on October 24, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. This case concerns the ability of the Department of Health and Human Services to recover overpayments made to health care providers under the Medicare program. Medicare, which was established

by the Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 291, provides health insurance that covers costs of hospital and related services (under Part A) and certain other supplementary services (under Part B) for aged and disabled persons. Gov't C.A. Br. 3. Under Part A, at issue here, participating health care providers that have furnished services to an eligible beneficiary submit a claim for payment to a fiscal intermediary. *Id.* at 3-4.

The intermediary reviews the claim and authorizes payment if the services provided are covered by the Act and the costs incurred are reasonable. Only coverage determinations are at issue in this case. Gov't C.A. Br. 4-5. The Act generally defines what constitutes covered services, see 42 U.S.C. 1395d, and excludes certain services from coverage, see, *e.g.*, 42 U.S.C. 1395y. In particular, the Act excludes services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury," and services constituting "custodial care." 42 U.S.C. 1395y(a)(1)(A) and (9). If the fiscal intermediary determines that a submitted claim is not for covered services, it must then determine whether, under 42 U.S.C. 1395pp(a), payment should nonetheless be made because neither the provider nor the beneficiary knew or could reasonably be expected to know that the services were not covered. The beneficiary (as opposed to the provider) is presumed to have been without such knowledge unless he received written notice informing him that the services were not covered. 42 C.F.R. 405.332, 405.334 (1989).[1] In contrast, providers are presumed, based, *inter alia*, upon common

[1] The relevant regulations were amended and redesignated during the pendency of this litigation. See 54 Fed. Reg. 41,733-41,734 (1989). For the convenience of the Court, we will cite the regulations in their pre-redesignation form.

industry practice, to have knowledge that certain services are not covered. 42 C.F.R. 405.336 (1989).

If the beneficiary is excused from payment—and if the provider is presumed to have had the requisite knowledge—it is responsible for payment. Thus, if the beneficiary has paid the provider for the services, the government will reimburse him and seek to recover from the provider, 42 U.S.C. 1395pp(b); if the government has already paid the provider for non-covered services, those amounts will be recouped by withholding from future payments to the provider. See 42 U.S.C. 1395gg(b).

Pursuant to 42 U.S.C. 1395ff(a), which provides that claims shall be determined by the Secretary "in accordance with the regulations made by him," a multi-layer process of review has been established for individuals who are dissatisfied with coverage and waiver determinations by a fiscal intermediary. See Gov't C.A. Br. 6-7; 42 U.S.C. 1395ff, 1395pp. The process of review includes reconsideration by the fiscal intermediary, an evidentiary hearing before an administrative law judge (provided the amount in controversy is at least $100), review by the HHS Appeals Council, and finally judicial review (provided the amount in controversy is at least $1000). See *Heckler* v. *Ringer*, 466 U.S. 602, 605-607 (1984). Providers may seek review under the same procedures in situations where they may be liable for the cost of non-covered services and the Secretary determines that the beneficiary will not exercise his right of review. 42 U.S.C. 1395pp(d).

2. Petitioners are three home health care providers that submitted thousands of Medicare claims for services provided to eligible individuals, and received payment under Medicare Part A on those claims. Pet. App. 2a-5a. Based on a tip that two of the petition-

ers had been overbilling Medicare and on data showing that the third petitioner's claims were much higher than those of comparable providers, the Department conducted post-payment audits of the claims submitted by petitioners. *Id.* at 4a-5a. As part of these post-payment audits, the Department examined a statistically significant number of randomly selected claims for the periods in question, and examined those claims and their medical documentation to determine whether there was a pattern of billing Medicare for services that petitioners knew or should have known were not covered by the Act. *Id.* at 5a. The audits revealed that there was a statistical pattern of billing Medicare for non-covered services. Based on an extrapolation from this statistically valid evidence, the Secretary sought to recoup the overpayments made to petitioners. *Id.* at 4a-5a.

Petitioners challenged the initial non-coverage determination with respect to the individual sample claims, and they largely prevailed in the administrative review process. Pet. App. 4a-5a, 16a. The ALJ concluded that the Secretary was time-barred under applicable regulations from reopening the targeted claims of petitioner Bayonne Visiting Nurse Association, and all funds withheld from Bayonne to recoup the overpayments were repaid with interest. The overpayments that the intermediary found to have been made to petitioner Chaves County Home Health Services were reduced after an ALJ hearing from approximately $47,000 to $11,688.76. And the ALJ reversed a number of the overpayment determinations in the sample of claims submitted by petitioner Albuquerque Visiting Nurse Association, thereby substantially reducing the total of approximately $138,000 in overpayments found by the intermediary. Gov't C.A. Br. 9-13.

3. a. Petitioners brought suit in federal district court, alleging that the use of statistical sampling as an auditing technique violated the Medicare Act, the Administrative Procedure Act, and their rights to due process under the Fifth Amendment.[2] The district court granted the Secretary's motion for summary judgment, Supp. App. 1-8, finding that "the judicial authority presently available overwhelmingly supports the proposition that statistical sampling in the readjudication of Medicare claims by HHS to determine overpayments and reimbursement liability is lawful." *Id.* at 8.

b. Petitioners appealed the district court's ruling, and the court of appeals affirmed. Pet. App. 1a-21a. The court of appeals held that the Secretary's established authority to conduct post-payment audits and recoup overpayments, which petitioners did not dispute, supported the Secretary's use of post-payment sampling audits. *Id.* at 7a-12a. Relying on established principles of statutory interpretation, see *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court of appeals first examined whether the language or structure of the Medicare Act showed that Congress had spoken directly to the issue of whether recoupment by statistically valid sampling is permissible. Finding no clear answer in the statute, the court explained that the Secretary's interpretation of the Act to allow such audits must be upheld if it is a permissible construction. Pet. App. 6a-7a. The court concluded that

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[2] Because petitioner Bayonne entirely prevailed in the administrative review process, it was not aggrieved by the Secretary's final decision and therefore had no right to judicial review under 42 U.S.C. 1395ff(b), which incorporates 42 U.S.C. 405(g).

the Secretary's interpretation is permissible, observing that vindicating the government's undoubted right to recoup overpayments through the device of statistical sampling "is reasonable given the logistical imperatives recognized by courts in other comparable circumstances." *Id.* at 12a.

The court of appeals rejected petitioners' argument that sampling affected the rights of beneficiaries, since sampling is not used to assess or recoup overpayments from them. Pet. App. 12a-15a. Further, the court held that allowing health care providers to challenge both the determination of non-coverage for each sample claim and the validity of the extrapolation from those determinations satisfies the providers' statutory review rights. *Id.* at 15a-17a. In the court's view, the alternative suggested by petitioners —that HHS can recoup overpayments only by reviewing every single claim and providing a separate review as to each—would impose a "daunting burden on the agency." *Id.* at 17a.

Finally, the court rejected petitioners' challenge to the legality of Health Care Financing Administration (HCFA) Ruling 86-1. That Ruling reaffirmed and explained the basis for HCFA's existing practice of using statistical sampling as an auditing technique. Pet. App. 19a-21a. The court explained that the Ruling is not the source of HCFA's authority, but rather constitutes only an explanation and reaffirmation of its practice of using post-payment sampling audits. *Id.* at 19a-20a. Accordingly, the court held that Ruling 86-1 is an interpretive ruling and, as such, was not subject to notice and comment rulemaking procedures mandated by the Administrative Procedure Act. For the same reason, the court concluded, its application

in the administrative proceeding here did not constitute retroactive rulemaking. *Id.* at 20a-21a.[3]

ARGUMENT

The decision of the court of appeals is correct, and does not conflict with any decision of this Court or of another court of appeals. It rests on a routine application of *Chevron* principles of deference to the interpretation of the Act by the agency charged with administering the vast and complex Medicare program, and it affirms the propriety of using statistically valid sampling methodologies in the post-payment audit setting that have long been recognized in the Medicare program. In fact, such sampling was used in the leading case sustaining the Secretary's right to recoup past overpayments under Medicare—*Mount Sinai Hospital of Greater Miami* v. *Weinberger*, 517 F.2d 329, 333, 343, modified, 522 F.2d 179 (5th Cir. 1975), cert. denied, 425 U.S. 935 (1976)—and has not been a recurring source of controversy in the sixteen years since that case was decided. Moreover, as petitioners' own experience shows, the administrative process affords a fair and effective procedure by which a provider may challenge overpayment determinations that are based on post-payment audits of a statistically valid sample of claims.

1. Petitioners' primary contention is that the Medicare Act prohibits the Secretary from recouping

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[3] In an argument that they do not renew in this Court, petitioners asserted in the court of appeals that the Secretary's practice of conducting post-payment sampling audits violates due process. The court rejected that argument, noting that the statistical reliability of the process and the strong governmental interest in recouping monies that had been wrongly paid justified the practice. Pet. App. 18a-19a.

overpayments through the device of statistical sampling, and that the court of appeals therefore erred in deferring to the Secretary's contrary interpretation under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). As the court of appeals determined, however, the Act itself does not furnish an answer to the question; specifically, nothing in its language or structure compels petitioners' interpretation. Nowhere in the Act is the notion of statistical sampling addressed, and post-payment recoupment by that method is not inconsistent with other provisions of the Act providing for review of claims at the prepayment stage. Proceeding to the second step of the *Chevron* analysis, the court of appeals correctly concluded that the Secretary's construction of the Act represents a reasonable accommodation of the rights of providers not to be subject to erroneous recoupment of previously paid claims, and the Secretary's undisputed right to protect the Medicare Trust Fund by recovering monies that providers have wrongfully obtained.

a. Petitioners concede (Pet. 22) that the Secretary has authority under the Medicare Act to conduct post-payment audits in order to recoup overpayments made to health care providers. See *Mount Sinai Hospital of Greater Miami* v. *Weinberger*, 517 F.2d at 343; *Wilson Clinic & Hospital, Inc.* v. *Blue Cross*, 494 F.2d 50 (4th Cir. 1974). The government's right to recover money that it has erroneously paid is established as an element of federal common law. Moreover, this right to audit past payments and recoup overpayments is confirmed in numerous Medicare Act provisions. See Pet. App. 9a; see, *e.g.*, 42 U.S.C. 1395y(f), 1395gg (b)(1). Petitioners contend, however, that this right of recoupment may not be exercised by examining a

statistically valid sample of a provider's claims to determine the number that were erroneously paid, and then extrapolating that figure to the relevant category of claims submitted by that provider. Pet. App. 6a.

b. As the court of appeals held, nothing in the Act either expressly allows or prohibits the Secretary's use of statistical sampling in carrying out his undisputed powers to audit and recoup. Pet. App. 12a. Contrary to petitioners' contention (Pet. 10-16), the court of appeals did not ignore 42 U.S.C. 1395ff, which governs determinations of Medicare claims. See Pet. App. 6a, 15a-16a, 17a. It noted petitioners' argument that Section 1395ff prohibits the use of sampling, and stated that it would be incompatible with the Act for statistical sampling to be used at the pre-payment stage with respect to the claims of individual beneficiaries. Pet. App. 6a. Nothing in the Act, however, expressly or impliedly deals with the question of procedures to be followed by the Secretary in recouping overpayments from providers on post-payment review. On that issue, the court of appeals held, the Act is silent.

Although petitioners contend that the Act's procedural provisions governing pre-payment coverage determinations should extend to post-payment recoupment audits, they do not explain why that is so. As the court below correctly noted, petitioners' contention fails to come to grips with the question of what "determination" is subject to review in the post-payment audit setting. See Pet. App. 15a-16a. Contrary to petitioners' contention that the Medicare Act guarantees providers a five-step review process (initial determination by the intermediary, reconsideration by the intermediary, review by an Administrative Law

Judge, review by the Appeals Council, and judicial review) for every one of the thousands of claims that may be in dispute on post-payment audit, it is reasonable to interpret the "determination" by the Secretary that is subject to review under Section 1395ff in the context of post-payment sampling audits as the findings regarding the sample claims and the validity of their extrapolation to the relevant category of the provider's claims. See Pet. App. 15a-16a.[4] Because the provider may contest that "determination" through the five-step review process, its statutory rights to review are fully protected. *Ibid.*

Moreover, as the court of appeals explained, the Secretary's interpretation of his recoupment authority is supported by precedent upholding the use of sampling audits to recoup overpayments in comparable circumstances. See Pet. App. 11a-12a; see, *e.g.*, *Illinois Physicians Union* v. *Miller*, 675 F.2d 151, 155 (7th Cir. 1982); *Michigan Dep't of Education* v. *United States Dep't of Education*, 875 F.2d 1196, 1204-1206 (6th Cir. 1989); *Georgia* v. *Califano*, 446 F. Supp. 404, 409-410 (N.D. Ga. 1977).

c. Petitioners and their *amici* assert that the enactment of Section 1395pp(d)—which extended to health care providers Section 1395ff's right to review of benefit determinations in certain circumstances, and which occurred after the events giving rise to the de-

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[4] Contrary to petitioners' contention (Pet. 23-24), the Secretary's use of statistical sampling is not inconsistent with the regulations promulgated under the Act. As the court of appeals held, the regulations in question, 42 C.F.R. 405.701-405.750, deal not with procedures for post-payment recoupment of overpayments, but rather with the right of providers and beneficiaries to individualized determination of benefits on initial review of claims. Pet. App. 17a.

cision in *Mount Sinai Hospital*—establishes that Congress intended Section 1395ff's procedures to apply in the post-payment setting in a manner that precludes reliance on sample audits, and instead requires separate rulings and review procedures as to each of thousands of claims.[5] Pet. 26 n.5; American Hospital Ass'n *et al.* Amici Br. 17. But even if the statute might reasonably be read as petitioners suggest, petitioners are incorrect that theirs is the only permissible reading. As explained above, on post-payment review involving a sampling audit, Section 1395ff is given effect by providing health care providers with a right to review of the determination that results from examination of a representative sample of claims and statistically valid extrapolation of the result to the entirety of their claims. Given the established right of the Secretary to recoup overpayments, there is no reason to conclude that enactment of Section 1395pp was intended to impose particular procedures on the exercise of that right.

2. a. Nor can petitioners establish that the Secretary's interpretation is unreasonable. Petitioners do not contend that sampling audits lead to unfair or invalid overpayment findings. A provider is furnished with a full opportunity to challenge the coverage determinations and waiver of liability findings made as to every claim in the sample group, Pet. App. 15a-16a, 8c-9c, and the extrapolation is reduced to the extent its challenge is successful. The provider may also challenge the validity of the sample, statistical assumptions, and extrapolation from the sample.

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[5] Petitioners are incorrect in contending (Pet. 26) that *Mount Sinai Hospital* did not take account of Section 1395pp. See *Mount Sinai Hospital*, 517 F.2d at 341 & n.22; 522 F.2d at 180 (opinion on rehearing).

Ibid. Petitioners have offered no reason, and we know of none, to think that this process yields anything other than fair and accurate results.[6] Health care providers have no entitlement to retain monies obtained from Medicare for services that they knew or should have known were not covered by the Medicare Act, and the Act should not be interpreted in a manner that would interpose significant barriers to the use of such fair procedures to recoup repayments.

b. Petitioners assert (Pet. 20) that the court of appeals' decision effectively licenses the Secretary to turn the prepayment claim review process of individual beneficiary claims into a "sham." To the contrary, the court specifically stated that post-payment sampling audits may *not* be used by HHS as a substitute for individualized pre-payment review. Pet. App. 13a-15a. Further, the court recognized that the Secretary's sampling audits are not directed against individual beneficiaries and may not be used to recoup an overpayment from an individual. *Ibid.*; see also Pet. 25.[7] The court merely held that where a provider

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[6] The reliability is enhanced by the fact that the sampling method allows both the provider and the agency to focus their attention and resources on adjudicating sample claims. The non-coverage determinations for particular claims must survive rigorous review before they are extrapolated; and no extrapolation is done unless there is a statistical pattern of wrongful payment manifested by the sample claims.

[7] Petitioners contend that the procedure, in effect, deprives providers of their right to recover benefits paid to individuals in certain circumstances. This argument is incorrect. The post-payment review process ensures that sample claims are decided adversely to providers only if they knew or should have known that the services at issue were not covered, a circumstance in which, by definition, providers have no recourse against individual beneficiaries. Moreover, beneficiaries have

is suspected of having a pattern of charging Medicare for services that it knows or should know are not covered by the Medicare Act, it is not inconsistent with the Act for the Secretary to supplement prepayment review with a post-payment sampling audit.

c. Petitioners extravagantly assert (Pet. 24) that sampling audits place the entire Medicare reimbursement system "at risk." Quite the reverse is true: it is the inability to use such audits that would put the system at risk. Without use of sampling as a post-payment auditing technique, there would be no feasible means of recouping Medicare overpayments. The amount of overpayment on any particular claim may be small, but the aggregate overpayment to the provider very significant. If individual treatment of each claim on post-payment audit were required, the costs of recoupment would outstrip the amounts recovered. Cf. *Sullivan* v. *Everhart*, 494 U.S. 83, 94-95 (1990). Thus, the choice is essentially between using a reliable sample auditing technique or allowing providers to retain undeserved gains that were obtained contrary to law. Pet. App. 12a.

3. Finally, the court of appeals correctly rejected petitioners' arguments (Pet. 26-27) that HCFA Ruling 86-1 was subject to notice-and-comment rulemaking and that the Ruling could not be applied "retroactively" to them. Notice-and-comment rulemaking is not required for interpretive rulings. See 5 U.S.C. 553(b)(A); *American Hospital Ass'n* v. *Bowen*, 834

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no repayment obligation unless they have received written notice that the services at issue are not covered. In such circumstances, providers can hardly complain about lack of an opportunity for repayment if they nonetheless submitted the claims to the government for repayment despite prior notice to the beneficiary of non-coverage.

F.2d 1037, 1045 (D.C. Cir. 1987). Ruling 86-1 is nothing more than an interpretive rule setting forth the agency's view of existing law and procedures. See *Mile High Therapy Centers, Inc.* v. *Bowen*, 735 F. Supp. 984, 985-986 (D. Colo. 1988) (HCFA Ruling 86-1 is an interpretive rule). As the court of appeals held, "the Ruling was not the source of [the] administrative authority in these cases but merely explained and reaffirmed the Department's long-standing and well-established practice of conducting sample audits." Pet. App. 19a-20a. It follows that application of the principles set forth in the Ruling to petitioners' cases is not impermissibly retroactive. Pet. App. 19a-20a. Petitioners' legal obligations were the same both before and after the Ruling was issued.

Petitioners contend (Pet. 26) that the court of appeals erred as a factual matter in concluding that there was a long-standing practice of using sampling audits. To the contrary, as other courts have recognized as well, the practice of using sampling audits dates back at least two decades. See *Mount Sinai Hospital*, 517 F.2d at 333 (upholding Secretary's use of a sampling post-payment audit to recoup $6.3 million); *Daytona Beach General Hosp., Inc.* v. *Weinberger*, 435 F. Supp. 891, 894-896 (M.D. Fla. 1977) (discussing the use of sampling audits in Medicare case in the early 1970s). Moreover, the court below correctly observed that the internal Medicare manual that petitioners themselves brought to the court of appeals' attention confirms the longstanding use of sampling audits, Pet. App. 20a, and numerous other Medicare manuals dating at least as far back as 1975 provide for sample audits to recover overpayments for non-covered services. See, *e.g.*, *Medicare Intermediaries Manual* § 2229 & Sampling Guidelines Appen-

dix (Dec. 1975); *Medicare Intermediaries Manual* § 3799.6 (Jan. 1977); *Medicare Intermediaries Manual* § 3710.3 (June 1979), *Medicare Intermediaries Manual* § 3710.3 (Oct. 1986); *Medicare Carrier's Manual* §§ 7150-7158 (July 1989); *Medicare Intermediaries Manual* § 2229 (July 1990).[8] Accordingly, the decision below involves no novel principle in the administration of the Medicare program.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JANUARY 1992

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[8] For this reason, *amici* American Hospital Association, et al., err in relying (Br. 16) on the extra-record letter from former Secretary Bowen to the Comptroller General. See *id.* at 1c-3c. That letter was brought to the attention of the court of appeals, see Gov't C.A. Br. 45, and it did not affect that court's conclusion that HCFA has long followed the practice of using sampling audits to recoup Medicare overpayments. Moreover, the letter does not reflect the basis for that practice in Ruling 86-1, the manuals cited in the text above, and cases dating from the 1970s.

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No. 91-674

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

CHAVES COUNTY HOME HEALTH SERVICE, INC., ALBUQUERQUE VISITING NURSING SERVICE, INC., AND BAYONNE VISITING NURSE ASSOCIATION, INC.,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D.,
Secretary of Health and Human Services,
Respondent.

BRIEF OF AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMICI CURIAE:

American Hospital Association
Federation of American Health Systems
American Association of Homes for the Aging
American Federation of Home Health Agencies
Home Health Services and Staffing Association

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INTEREST OF AMICI CURIAE

The amici curiae are four national associations that represent virtually every type of facility qualifying for participation in the Medicare program as a "provider of services." 42 U.S.C. § 1395x(u).[1]

The American Hospital Association ("AHA") is the primary national membership organization of hospitals in the United States. Its membership includes approximately 5,400 hospitals and other health care institutions, as well as over 50,000 personal members. Virtually every AHA institutional member is a Medicare provider.

The Federation of American Health Systems is a national organization representing investor-owned companies that own over 1,300 hospitals and manage an additional 345 non-profit hospitals, a majority of which are Medicare and Medicaid certified.

The American Association of Homes for the Aging ("AAHA") is an association representing approximately 3,900 non-profit, long-term health care facilities ("nursing homes" or "nursing facilities") throughout the United States. Approximately 85% of AAHA's member facilities participate in the Medicare/Medicaid program.

The American Federation of Home Health Agencies ("AFHHA") is a national association representing home health agencies that participate in the Medicare program, as well as other entities and individuals who support the Medicare home health benefit. AFHHA's more than 135 Medicare-certified home health agency members include freestanding agencies, Visiting Nurse Associations, county agencies, hospital-based agencies, and members of chain organizations.

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[1] These providers all furnish services that are covered under Part A of the Medicare program which is at issue in this case, although members of these associations also provide services which are covered under Part B. Part A provides coverage for certain inpatient hospital services, post-hospital extended care services, home health and hospice services. 42 U.S.C. § 1395d(a). Part B provides coverage for certain outpatient and physicians' services. 42 U.S.C. § 1395k(a).

The Home Health Services and Staffing Association represents 16 national companies which operate approximately 700 Medicare-certified home health agencies in 46 states and the District of Columbia.

The Amici support the petition for a writ of certiorari filed in this case because the Secretary's sample adjudication scheme, as upheld by the court of appeals, jeopardizes their due process rights under the Medicare claims adjudication process to individualized factual determinations, notice and administrative and judicial review. Unless that decision is overturned, many hospitals, nursing homes and home health agencies will suffer severe financial damage and lose any meaningful opportunity for relief on appeal.[2]

STATEMENT OF THE CASE

A. The Secretary's Action

The Department of Health and Human Services' use of the sample adjudication scheme in this case represents the first instance in the 55-year history of the Social Security Act that the agency has sought to abolish the right to factual determinations, notice and appeal on individual claims under the formal claims adjudication process prescribed by the statute. The Social Security Act and its implementing regulations establish a four-step administrative process for the review and adjudication of claims: (1) an initial determination of the facts pertaining to a particular claim, (2) reconsideration of an adverse initial determination, (3) a hearing before an administrative law judge of an adverse reconsideration determination, and (4) Appeals Council review of any adverse hearing determination. *See* 42 U.S.C. §§ 405(a),(b); 20 C.F.R. §§ 404.929-404.961 A claimant who is dissatisfied at the end of the administrative review process may obtain judicial review. 42 U.S.C. § 405(g). If the Secretary decides to revise a

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[2] The consents of the parties to the filing of this brief have been filed with the Court.

determination, it must be reopened, and that determination may then be reviewed under the standard four-step process. 20 C.F.R. § 404.992.

This formal claims adjudication process has been used consistently for five decades to adjudicate coverage of claims under Title II (the Old-Age, Survivors, and Disability Insurance Program), Title XVI (the Supplemental Security Income Program) and Part A of Title XVIII (the Health Insurance for the Aged and Disabled Program or "Medicare"). *See generally Bowen v. Yuckert*, 482 U.S. 137, 141-43 (1987); *Heckler v. Day*, 467 U.S. 104, 108 (1984); *Heckler v. Ringer*, 466 U.S. 602, 606-07 (1984). *See also* K. Davis, Administrative Law Treatise § 10:3, p. 313 (2d ed. 1979).

In this case, the Secretary used an unpublished sample adjudication scheme to readjudicate and deny thousands of Medicare Part A claims that had been found covered under the formal Social Security claims adjudication process. The basis for most of the denials was the Secretary's determination that the services were not medically necessary. Although the Secretary reviewed the *sample* claims under the formal adjudication process, he projected the percentage of denied sample claims to a universe of other factually distinct claims which he readjudicated without *any* individualized factual review or determination and without even identifying the specific claims that were denied. The Secretary's sole reason for suspending the formal Social Security claims adjudication process on readjudication was that, in his view, it would not be cost effective. Petitioners' Appendix ("Pet. App.") at 5c.

B. The Proceedings Below

This action was commenced on September 29, 1986 but the district court delayed its decision for nearly four years "in hopes that further guidance might be forthcoming from the U.S. Supreme Court or a circuit court of appeals." Petitioners' Supplemental Appendix ("Pet. Supp. App.") at 3. The district court upheld the Secretary's sample adjudication scheme without any analysis of the statutory or

regulatory provisions establishing the Part A claims adjudication process and, instead, relied on decisions interpreting different adjudicatory schemes under the Medicaid statute and Part B of the Medicare Act.[3]

The court of appeals found the question "close" but held that sample adjudication could be reconciled with the requirements for case-by-case review and appeal under the Part A claims adjudication process. Pet. App. at 21a. In reaching its determination, the court correctly determined that

> (a) The issue in this case concerns exclusively the method prescribed by Congress for adjudicating coverage of Part A Medicare claims;[4]
>
> (b) The Part A claims adjudication process set forth in the Medicare statute, regulations and instructions requires individualized factual determinations based on case-by-case review, notice and appeal;[5]
>
> (c) The statute confers precisely the same rights to the Part A claims adjudication process upon individual beneficiaries and providers;[6] and
>
> (d) Neither the statute, legislative history, regulations nor agency policy statements mention the use of sampling to adjudicate unreviewed Medicare Part A claims.[7]

The court upheld the Secretary's use of sample adjudication to readjudicate previously approved claims on the assumption that the rights to individualized factual deter-

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[3] The district court found subject matter jurisdiction under 42 U.S.C. § 405(g) based upon the conclusion that Petitioners had effectively exhausted all administrative remedies. Pet. Supp. App. at 3 n.2.

[4] Pet. App. at 3a.

[5] Pet. App. at 6a, 12a-13a, 17a-18a.

[6] Pet. App. at 13a-14a, 15a.

[7] Pet. App. at 5a, 17a.

minations, notice and appeal under the Medicare Part A claims adjudication process are only available on "prepayment" review and not on "post-payment" review. Pet. App. at 6a, 15a. Although the court found no support for that distinction in the statute, legislative history or regulations, it concluded that such silence warranted deference to the agency's action. Pet. App. at 21a.

The court further held that Petitioners' constitutionally protected property interest in retaining payment for services provided to Medicare beneficiaries had not been denied without due process because they were given an opportunity to contest the denied *sample* claims and the statistical validity of the samples. Pet. App. at 18a-19a.[8]

The court also held that, despite the fact that the sample adjudication scheme was fundamentally different from the claims adjudication process set forth in the statute and regulations, it was not applied in violation of the rulemaking requirements of the Administrative Procedure Act solely because, in the court's view, it was a "longstanding and well-established practice." Pet. App. at 19a-20a.

For the same reason, the court concluded that the scheme, as set forth in HCFA Ruling 86-1, was not applied retroactively, even though the ruling was issued subsequent to the Secretary's use of sampling in this case, and was the sole authority for the final administrative determinations adverse to Petitioners. *See* Pet. App. at 19a-21a.

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[8] The court erroneously concluded that Petitioners failed to "timely and specifically challenge the statistical validity of the sample procedure as applied to them." Pet. App. at 6a, 16a, 19a. In fact, all three Petitioners challenged the statistical validity of the samples in the context of the appeals on the merits of the denied sample claims. *See, e.g.*, Am. App. at 8b. Petitioners also noted before the district court, and in their reply brief before the court of appeals, that the validity of the samples had been placed in issue. *See* Appellants' Reply Brief at p. 2 n.2, *citing* Plaintiffs' Statement of Genuine Issues.

REASONS FOR GRANTING THE WRIT

A. The Court of Appeals' Decision Conflicts With Holdings Of This Court That The Social Security Claims Adjudication Process Requires Individualized Factual Determinations, Notice and Appeal

The court of appeals' decision ignores a statutory scheme which has been recognized and upheld by this Court for twenty years. The Medicare statute incorporates the formal claims adjudication process which was prescribed by, and developed under, Title II of the Social Security Act. *See* 42 U.S.C. §§ 405(a)(b),(g) as incorporated by 42 U.S.C. § 1395ff, 1395ii. *See also Heckler v. Ringer*, 466 U.S. 602 606-07 (1984). The four-step claims adjudication process leading to judicial review was established as early as February 1947 for the adjudication and review of claims arising under Title II. 12 Fed. Reg. 570 (1947). That process was incorporated into Title XVIII in 1965 but made available only to Medicare beneficiaries for determinations of coverage under Part A. Pub. L. No. 89-97, § 102 (1965), *codified at* 42 U.S.C. § 1395ff(b). *See* 42 C.F.R. §§ 405.701-405.750. The Social Security claims adjudication and review process was extended to providers in 1972 for Medicare Part A claims denied for lack of medical necessity in cases where liability was not waived. Pub. L. No. 92-603, § 213(a) (1972), *codified at* 42 U.S.C. § 1395pp(d). In 1986, the process was extended to providers, beneficiaries, physicians and suppliers for claims under Part B. Pub. L. No. 99-509, § 9341(a)(1)(A-D)(1986), *codified at* 42 U.S.C. § 1395ff(a),(b).

This Court has analyzed the requirements of the formal claims adjudication process mandated under Title II at least nine times. On each occasion, the Court has observed that the process requires individualized factual determinations, notice of those determinations, and administrative and judicial review. *See Richardson v. Perales*, 402 U.S. 389, 394-98 (1971); *Mathews v. Eldridge*, 424 U.S. 319, 339-40 (1976); *Califano v. Yamasaki*, 442 U.S. 682, 687-88 (1979); *Heckler v. Campbell*, 461 U.S. 458, 468 (1983);

Heckler v. Day, 467 U.S. 104, 107-08 (1984); *Bowen v. City of New York*, 476 U.S. 467, 471-73 (1986); *Bowen v. Yuckert*, 482 U.S. at 140-43; *Schweiker v. Chilicky*, 487 U.S. 412, 424 (1988); and *Sullivan v. Zebley*, ___ U.S. ___, 110 S. Ct. 885, 888, 890 (1990). The Court has noted that the claims adjudication process required by Title II is evidence of Congress' intent to be "unusually protective" of the rights and interests of claimants. *Heckler v. Day*, 467 U.S. at 106. *See also Chilicky*, 487 U.S. at 424; *Bowen v. City of New York*, 476 U.S. at 480.

Specifically, this Court has held that individualized factual determinations and review are required under the Social Security claims adjudication process where the unique medical condition of a beneficiary must be determined based on historical facts. *Campbell*, 461 U.S. at 467-468. *Accord Zebley*, 110 S. Ct. at 890; *Bowen v. City of New York*, 476 U.S. at 485. In addition, this Court has held that both the statutory scheme and the due process clause of the Constitution require that review to include an opportunity for an oral hearing on issues of credibility which are involved in waiver of liability or waiver of recoupment determinations. *Yamasaki*, 442 U.S. at 697-98; *Eldridge*, 424 U.S. at 345.[9]

In confirming the right to individualized factual determinations under the Social Security claims adjudication process, this Court has flatly rejected the kind of administrative burden arguments advanced by the Secretary in this case. According to the Court, any decision process that fails to take into account "the infinite variety of medical conditions and combinations thereof, the varying impact of such conditions due to the claimant's individual characteristics, and the constant evolution of medical di-

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[9] The Court has noted that although the Secretary may rely on rulemaking to resolve certain "classes of issues" he may not rely on such a process to avoid making individualized determinations on facts that are unique to each beneficiary. *Campbell*, 461 U.S. at 467-68. *See also American Hospital Association v. NLRB*, ___ U.S. ___, 111 S. Ct. 1539, 1543 (1991); *Mobil Oil Exploration v. United Distrib. Co.*, ___ U.S. ___, 111 S. Ct. 615, 626 (1991).

agnostic techniques," cannot fulfill the statutory mandate for individualized factual determinations. *Zebley*, 110 S. Ct. at 896. *See also Bowen v. City of New York*, 476 U.S. at 488.[10]

As the court of appeals noted, coverage and waiver determinations under Part A require the kind of assessment of unique historical medical facts and credibility which this Court has held must be made in individualized factual determinations under the Social Security claims adjudication process.[11] Thus, the court's holding that the Secretary can readjudicate thousands of unidentified, factually distinct Medicare Part A claims without making individualized factual determinations, or even identifying the specific claims, conflicts with twenty years of unbroken Supreme Court precedent.

The court of appeals' conclusion that sample adjudication results in merely a "monetized estimate," rather than in the denial of some particular, unidentified claims outside the sample, rests on a fundamental misunderstanding of

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[10] The administrative burden of providing individualized determinations and appeals is not overwhelming since the Secretary has conceded that those rights must be afforded if a claim is denied when initially presented. Pet. App. at 8c-9c. Moreover, hearing requests for both Medicare Part A and Part B claims, without the use of sample adjudications, constituted only 4% of the total hearing requests under the Social Security claims adjudication process in fiscal 1990. Social Security Administration 1991 Annual Report to Congress, 32 (May 1991). In any event, the Petitioners do not contest the Secretary's common law right to recoup lawfully determined overpayments or the use of post-payment sample review to determine whether a particular type of claim should be reopened and individually readjudicated. In fact, the Secretary currently uses sampling in just this manner to identify inpatient hospital services for individualized determinations on post-payment review. *See* the peer review program described in *American Hospital Association v. Bowen*, 834 F.2d 1037, 1049 (D.C. Cir. 1987).

[11] Payment to a provider on behalf of a beneficiary depends upon (a) whether a specific item or service was medically necessary in view of the patient's unique medical condition (42 U.S.C. § 1395y(a)(1)) and, if not, (b) whether the provider's or the beneficiary's liability should be waived because one or both did not know that the service would not be covered (42 U.S.C. § 1395pp(a)-(c)). Pet. App. at 3a.

the Title II/Medicare Part A claims adjudication process. Pet. App. at 15a-16a.

First, and foremost, both Titles II and XVIII provide a single detailed adjudication and review process for *all* claims *regardless* of when the claim review or denial takes place. 42 U.S.C. § 1395ff(a),(b) and 405(b),(g). Under that process, the *only* method by which the Secretary can assert the existence of an overpayment based on previously paid claims is to reopen and revise individual favorable initial coverage determinations. 42 C.F.R. § 405.750. *See* 20 C.F.R. § 404.987.[12]

The court's misunderstanding of the Part A claims adjudication process led it to the erroneous conclusion that the process on reopening is somehow different than the process when claims are initially presented. Pet. App. at 15a. In fact, the regulations give providers and beneficiaries the right to seek review under the Title II/Part A claims adjudication process of any initial determination that is issued after a reopening. 42 C.F.R. §§ 405.704(b), 405.710. *See* 20 C.F.R. §§ 404.992, 404.993.[13] Therefore, the claims adjudication process under Titles II and XVIII applies *whenever* claims are adjudicated and denied, and

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[12] The Title II/Part A claims adjudication process states that providers and individuals are entitled to rely on the finality of an initial favorable determination on a claim until that initial determination is reopened and revised. 42 C.F.R. § 405.708. *See* 20 C.F.R. § 404.905. The regulations expressly state that, in the absence of such a reopening and revision, the initial determination is "final and binding." *Id. Draper v. Sullivan*, 899 F.2d 1127, 1130-31 (11th Cir. 1990); *Taylor v. Heckler*, 765 F.2d 872, 876-77 (9th Cir. 1985).

[13] *See also* Title XVIII Administrative Finality—Reopening and Revising Part A and Part B Determinations and Decisions, § 04060.060, Notice of Results of Reopening, HHS Program Operations Manual (1982):

> The right to reconsideration, review, or hearing applies to the entire determination, not just the part revised.

Thus, the "crucial gap," the fulcrum of the decision below, was not in Petitioners' position, but, rather, in the court's understanding of the Title II/Part A claims adjudication process. Pet. App. at 15a.

the Secretary cannot suspend that statutory and regulatory scheme in seeking to assess an overpayment.

B. Sample Adjudication Conflicts With The Statutory Scheme and Deprives Providers Of Their Rights To Appeal And To Receive Payment For Their Services

The statutory scheme provides that, when a claim is denied for a lack of medical necessity, providers have a right to notice and administrative and judicial appeal of those individual denied claims. 42 U.S.C. §§ 1395h(j), 1395ff(b), 1395pp(d). Congress has balanced the administrative burden of these due process rights against the need for accuracy and fairness to providers, and has provided for administrative hearings for denied Part A claims where $100 or more is in controversy and for judicial review where $1,000 or more is in controversy. 42 U.S.C. § 1395ff(b)(2).

As the court of appeals correctly noted, sample adjudication "would be inconsistent with the statute" if it supplanted this statutory scheme. Pet. App. at 6a. Yet that is precisely its effect. The Secretary used the sample adjudication scheme to erase the favorable determinations rendered under the process mandated by the statute and regulations as though they never existed. Sample adjudication was, therefore, not a supplemental process, but rather, the *exclusive* process by which denied claims were adjudicated.

The Secretary also used the sample adjudication scheme to deny claims far in excess of the amounts qualifying for administrative and judicial review and to prevent Petitioners from obtaining that review. The Secretary computed the overpayments by projecting the sample denials to the *universe* of claims but determined the amount in controversy for appeal purposes based solely on the face amount of each individual *sample* claim, many of which were below the jurisdictional amounts. Petitioners were thereby denied the opportunity for administrative hearings and judicial review on numerous sample claims used by

the Secretary to deny thousands of dollars worth of claims in the universe far in excess of the jurisdictional amount thresholds established by Congress. *See, e.g.*, Order of Appeals Council Dismissing Request for Hearing (Apr. 4, 1988). Am. App. D.

Petitioners further lost the right to appeal certain denied sample claims by aggregating them with denied claims in the universe for the same individuals, as permitted by regulation. 42 C.F.R. § 405.740(e),(f)(2). Petitioners also lost the right to appeal even those individual claims in the universe that met the jurisdictional amount requirements since the claims were unidentified. The sample adjudication scheme was thus used to disrupt the balance that Congress has struck between administrative convenience and the fairness and accuracy of the Title II/Part A claims adjudication procedures.[14]

The court of appeals' holding provides an economic incentive for the Secretary to conduct only the most cursory and inaccurate review when claims are initially presented. If he denies a claim for a provider or a beneficiary at that stage, he must provide the review and appeal rights contained in the Part A claims adjudication process. If he simply waits (2 years, a month or 10 minutes) to deny claims on post-payment review, he can ignore the providers' and beneficiaries' rights and impose the sample adjudication scheme. Thus, by simply reserving denials for post-payment review as he did in this case, the Secretary is free to deprive providers and beneficiaries of the statutory rights recognized by the court of appeals.

At least as significantly, the sample adjudication scheme also abrogates the congressionally recognized rights of

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[14] Loss of those procedures can be extremely significant for providers, as illustrated by the fact that Petitioners obtained a reversal in their favor of nearly every denied sample claim that was reviewed by an administrative law judge. Pet. at 4. The Petitioners' experience on appeal was hardly unique since a study ordered by Congress found that 76% of the denied home health claims reviewed by administrative law judges were reversed in favor of the providers. *See* Report to Congress of Advisory Commission on Medicare Home Health Care (July 1, 1989).

providers to be paid for their services. The Medicare program is a health insurance program, and where claims are denied for lack of medical necessity, providers are entitled to exercise their rights under state law to seek payment from the individual who received the services.[15] Of course, providers cannot assert their rights to payment for services when the sample adjudication scheme is used because it is impossible to determine which individuals' claims in the universe have been denied. If providers cannot be compensated, either under the Medicare health insurance program or by the patient who received the services, the uncompensated costs must be borne by other patients or the services cannot be provided.

The court of appeals' holding that the Petitioners' rights to payment were not denied is based on a misunderstanding of the statutory scheme. Pet. App. at 14a. The court incorrectly assumed that providers may only seek payment from beneficiaries when coverage is denied and the Secretary decides not to waive the beneficiaries' liability. *Id.* The statute and its legislative history clearly provide that the provider may seek payment in *any* case from an individual whose claims are denied for lack of medical necessity. 42 U.S.C. § 1395pp(b),(c); S. Rep. No. 92-1230, 92d Cong., 2d Sess. 294 (1972). The Secretary's determination with respect to waiver of the beneficiaries' liability only affects whether the Secretary will indemnify the individual for the payments to the provider. 42 U.S.C. § 1395pp(b).

Thus, the congressionally recognized rights of providers to be paid for non-covered services are simply extinguished by the Secretary's sample adjudication scheme.

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[15] These rights have been recognized by Congress, the courts and the Secretary since the inception of the Medicare program. *See* S. Rep. No. 92-1230, 92d Cong., 2d Sess. 294 (1972); *Highland District Hospital v. Sec'y of HHS*, 676 F.2d 230, 238 (6th Cir. 1982); *Alabama Hospital Ass'n v. U.S.*, 656 F.2d 606, 614-15 (Ct. Cl. 1981), *cert. denied*, 456 U.S. 943 (1982); HCFA Ruling 83-1 (1982).

C. The Court Of Appeals' Decision Conflicts With The Statutory Analysis Required By Decisions Of This Court

As this Court has held, when a court reviews an agency's construction of the statute it administers, the first step is to determine, based upon the statutory provisions at issue as well as the language and design of the statute as a whole, whether Congress has expressed its intent with respect to the precise question at issue. *Sullivan v. Everhart*, ___ U.S. ___, 110 S. Ct. at 964; *Bethesda Hospital Ass'n v. Bowen*, 485 U.S. 399, 403-07 (1988); *Chevron U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837, 842-44 (1984). If the intent of Congress can be clearly determined, then that intent must be given effect by the court and by the agency. *Chevron*, 467 U.S. at 842-44. If the intent of Congress cannot be determined, then the court may proceed to the second step and defer to the agency's consistent interpretation, but only so long as the court finds that it is a reasonable accommodation of conflicting policies delegated to the agency's discretion, and that accommodation is one the court finds Congress would have sanctioned. *Chevron*, 467 U.S. at 845.

The precise issue of statutory construction in this case is whether Congress intended for Part A Medicare claims to be adjudicated on an individualized basis with notice and an opportunity for administrative and judicial review of those determinations. The court agreed with Petitioners that such intent was plainly expressed in the statute. Pet. App. at 6a, 12a-13a. Having found clear congressional intent to provide for individualized determinations of Part A claims, the court could not logically assume a contrary intent for post-payment review without some hint from statutory language or legislative history.[16] Such a principle

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[16] The statutory section prescribing the Title II claims adjudication process has been amended 37 times since its enactment in 1935, and the companion sections in Title XVIII have been amended 10 times since that statute was enacted in 1965. Congress has never given the slightest indication that the Secretary is authorized to adjudicate claims

of statutory analysis would require Congress to indicate not only what it means in conferring rights but also to list everything it does not mean.

The court also failed to consider the language and design of the statute as a whole by dismissing major statutory provisions which were inconsistent with its conclusion on the grounds that they were "not implicated in this case." Pet. App. at 13a. Statutory provisions accorded such treatment included (a) the provision that requires intermediaries to furnish "the provider and the individual with respect to whom the claim is made" a written explanation of the reason for each denial and prompt notification of the resolution of any reconsideration (42 U.S.C. § 1395h(j));[17] (b) the statutory provisions that require notice to the beneficiary "in each case" where coverage is denied but a claim is paid under waiver (42 U.S.C. §§ 1395pp(a),(b)); and (c) the statutory provision that states that payment to a provider under Title XVIII shall be deemed to be payment to the individual who received the services and requires the Secretary to retain the ability to identify and recoup overpayments from the individual in cases where the overpayment cannot be recouped from the provider or where the provider was "without fault" in causing the overpayment (42 U.S.C. § 1395gg(a),(b)). The court completely ignored the statutory provisions which require individual claim denials to be identified so that a determination can be made as to whether the jurisdictional amount in controversy requirements are met. 42 U.S.C. § 1395ff(b)(2). These provisions constitute clear evidence of congressional intent to require individualized determinations and appeal.

Even if the statute were ambiguous, the Secretary's interpretation in this case would not be entitled to deference because the statute and its legislative history clearly reveal that sample adjudication is not a process that Con-

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without making a determination on the unique facts pertaining to individual beneficiaries. *See* amendments to 42 U.S.C. §§ 405, 1395ff, 1395pp.

[17] *See* similar language in 42 U.S.C. § 405(b) and 42 C.F.R. § 405.702.

gress would have sanctioned. *Chevron*, 467 U.S. at 845. The amendments that Congress has made to the claims adjudication process under Titles II and XVIII since their original enactment have been directed uniformly toward broadening review and appeal rights on individual appeals and requiring more specific notice of adjudicated facts.[18] Accordingly, the court of appeals failed to apply either step of the *Chevron* test as prescribed by this Court.

Moreover, the court of appeals' decision conflicts with holdings of this Court which state that even a permissible interpretation of the statute is entitled to no deference if it is not supported by the agency's regulations, rulings or administrative practice. *See Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158, 171-72 (1989); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 211-13 (1988). It is further well-established that courts should not defer to agency interpretations which, as in this case, are inconsistent with earlier and later pronouncements. *See EEOC v. Arabian American Oil Co*, ___ U.S. ___, 111 S. Ct. 1227, 1235 (1991), *citing Skidmore v. Swift and Co.*, 323 U.S. 134, 140 (1944).

As the court of appeals conceded, the Secretary's long-standing regulations and policy statements consistently state that individual determinations and appeals are required to adjudicate Part A Medicare claims for providers and beneficiaries. 42 C.F.R. §§ 405.701-405.750; Pet. App. at 17a. The Secretary's sample adjudication policy was not set forth in any regulation, ruling or policy statement at the time it was applied to Petitioners.[19]

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[18] *See, e.g.*, Pub. L. No. 96-265, § 305(a) (1980) amending 42 U.S.C. § 405(b) to require more specific information to be provided when a claim is denied; Pub. L. No. 100-203, § 4032(a) (1987) amending 42 U.S.C. § 1395h to the same effect; Pub. L. No. 92-603, § 213(a) (1972) amending Title XVIII to extend the Title II adjudication process to providers; and Pub. L. No. 99-509, § 9341(a)(1)(A-D) (1986) amending 42 U.S.C. § 1395ff to extend the Title II claims adjudication process to Part B claims.

[19] As the court noted, HCFA Ruling 86-1 was issued *after* the Sec-

Furthermore, the Secretary stated in a signed statement to the General Accounting Office in November 1987 that sample readjudication of Part A home health claims would violate the Medicare statute and would be contrary to the longstanding congressional interest in protecting the rights of providers. *See* Letter from Otis R. Bowen, M.D., Secretary of HHS, to Charles Bowsher, Comptroller General (November 23, 1987). Am. App. C.

There can be no more authoritative source for the agency's longstanding interpretation of the statute than its own regulations and an interpretation signed personally by the Secretary. By contrast, "[d]eference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate." *Georgetown Univ. Hosp.*, 488 U.S. at 213.[20] Accordingly, the court of appeals' decision conflicts with this Court's established precedent that deference is not owed to an unpublished interpretation of the statute advanced by government counsel which is inconsistent with both preexisting regulations as well as the Secretary's subsequent interpretation of the statute.

D. The Court of Appeals' Decision Conflicts With The Rulemaking Requirements Of The Administrative Procedure Act As Recognized By This Court

It was undisputed before the court of appeals that the Secretary's sample adjudication policy was set forth only in HCFA Ruling 86-1, that it was "a rule" as defined in the Administrative Procedure Act (5 U.S.C. § 551(4)), and that it was never published in the *Federal Register* in compliance with the rulemaking requirements (5 U.S.C.

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retary's action was taken. Pet. App. at 19a. The court failed to recognize, however, that an instruction, on which it relied, was issued even later. *See* Intermediary Manual § 3799.5 (Aug. 1986). Pet. App. at 18a, 20a.

[20] The administrative law judge in the *Albuquerque VNS* case found that the interpretation of the statute set forth in HCFA Ruling 86-1 was merely the same argument which had been previously presented by government counsel in that very proceeding and rejected in a prehearing order. *See In the Case of Albuquerque Visiting Nursing Service, Inc.*, p. 14 (Sept. 29, 1986). Am. App. at 1b-2b.

§ 553). The court found that the rule was interpretative, and therefore exempt from the rulemaking requirements, solely based on the belief that sample adjudication for Part A Medicare claims was a "longstanding practice." Pet. App. at 21a. The court was wrong on both the facts and the law.

Sample adjudication is not a longstanding practice of adjudicating Part A claims. As shown, individualized factual determinations and appeal have been required under the Title II/Part A adjudication process by statute and by the holdings of this Court for five decades. Moreover, there is absolutely no reported prior instance of the Secretary even attempting to entirely delete the individual factual determinations, notice and appeal required under that process. Neither the decision in *Mt. Sinai Hospital v. Weinberger*,[21] nor in *Daytona Beach General Hospital v. Weinberger*,[22] supports that proposition. Both of those cases arose *prior* to the effective date of the 1972 amendments which extended the rights under the Part A claims adjudication process to providers. In any event, neither decision upheld, or otherwise endorsed, the Secretary's right to use sampling to readjudicate Part A Medicare claims even prior to the 1972 amendments. *See* Am. App. 5b-6b.

The court's reliance on the decision in *Mile High Therapy Centers, Inc. v. Bowen*[23] is similarly misplaced. That case involved the application of HCFA Ruling 86-1 to *Part B* Medicare claims prior to the effective date of the 1986 amendments which extended the Title II/Part A claims adjudication process to providers, beneficiaries, physicians and suppliers filing such claims.[24] Those amendments were effective for items and services furnished beginning Jan-

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[21] 517 F.2d 329, *modified*, 522 F.2d 179 (5th Cir. 1975), *cert. denied*, 425 U.S. 935 (1976).

[22] 435 F. Supp. 891 (M.D. Fla. 1977).

[23] 735 F. Supp. 984 (D. Colo. 1988).

[24] Of course, the sections of the Carriers Manual cited in the *Mile High Therapy* decision are irrelevant for the same reason. *See* Pet. App. at 20a.

uary 1, 1987. *See* Pub. L. No. 99-509, § 9341(a)(1)(A-D) (1986).[25] Thus, the court of appeals was absolutely incorrect in relying on those cases to conclude that the sample adjudication scheme constituted a longstanding interpretation of the Title II/Part A claims adjudication process at issue in this case.

Perhaps the clearest evidence that sample adjudication was not a longstanding interpretation is that, in 1986, the GAO suggested, without legal analysis, that the Secretary *begin* using the process on post-payment review. As discussed above, Secretary Bowen formally responded to the suggestion in 1987 by stating that such a process would be prohibited by statute. Am. App. C. Clearly, neither GAO, Congress, nor the Secretary has ever understood or maintained that sample adjudication of Part A claims was a longstanding practice, and, more specifically, the Secretary understood that such a change would require a statutory amendment.

Moreover, the court of appeals applied the wrong test for determining whether rulemaking is required. It is well-established that rules which have the binding effect of law and which change established law or policy are substantive rules that must be issued in compliance with the rulemaking requirements of the Administrative Procedure Act. *Chrysler Corp. v. Brown*, 441 U.S. 281, 316-17 (1979); *General Elec. Co. v. Gilbert*, 429 U.S. 125, 141 (1976); *American Hosp. Ass'n v. Bowen*, 834 F.2d at 1045. HCFA Ruling 86-1 was clearly binding because it was issued as a "ruling" and was the sole basis for the Appeals Council's decisions dismissing Petitioners' challenges to the sample adjudication scheme. *See Zebley*, 110 S. Ct. at 885 n.9. Furthermore, the sample adjudication scheme contained in the ruling altered Petitioners' rights to individual deter-

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[25] Although Amici believe the *Mile High* decision is incorrect, Congress has indicated that, at least beginning with 1987, the Part A claims adjudication process, including individualized factual determinations, notice and appeal, also applies to the adjudication and readjudication of Part B claims.

minations, notice and appeal set forth in the regulations governing Part A claims adjudication. *See* 42 C.F.R. §§ 405.701-405.750. Accordingly, even if the sample adjudication scheme had been "longstanding," the rule which gave it the binding effect of law simply could not be used to abolish established rights of providers under lawfully issued regulations without compliance with the APA rulemaking requirements. *See* 5 U.S.C. § 553(b).

E. The Retroactive Application Of HCFA Ruling 86-1 Conflicts With This Court's Holdings

The court of appeals correctly noted that, if HCFA Ruling 86-1 "changed HHS procedures," its use would be impermissibly retroactive. Pet. App. at 19a, citing this Court's holding in *Georgetown v. Bowen*. The ruling unquestionably changed the claims adjudication process to which Petitioners were entitled in 1984 and 1985 when they were initially subjected to the sample adjudication scheme. The ruling was not issued until February 20, 1986, and by its very terms, was only to be effective "on the date of issuance." Am. App. E. Yet, counsel for the Secretary sent the ruling to the administrative law judge in the *Albuquerque VNS* case and contended that he was compelled to reverse his prior holding that sample adjudications were not authorized for Part A claims adjudication. Am. App. at 2b. As stated above, the Appeals Council also subsequently relied on HCFA Ruling 86-1 in dismissing Petitioners' challenges to sample adjudication.

Neither the court of appeals nor the Secretary suggested that there is any express statutory authority for the Secretary to issue such a retroactive rule. In the absence of express congressional authorization under the Medicare Act, such rules can have no validity. *Georgetown Univ. Hosp.*, 488 U.S. at 213. The rule is also invalid under the Administrative Procedure Act because it changed rights under the claims adjudication process retroactively. 5 U.S.C. § 551(4). *Georgetown Univ. Hosp.*, 488 U.S. at 216-217 (J. Scalia concurring); *Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987).

CONCLUSION

The court of appeals decision jeopardizes the established rights of providers, physicians, suppliers, and beneficiaries nationwide to individualized factual determinations, notice and appeal under the Social Security claims adjudication process. To date, the Secretary has abolished the rights of only the Petitioners (and their patients) under that process. Amici urge the Court to accept this case and to resolve this issue of vital importance to the nation's health system before the Secretary takes further action to implement the sample adjudication scheme.

Respectfully submitted,

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APPENDIX

APPENDIX A

STATUTORY PROVISIONS

I. The Claims Adjudication Process Under Title II

A. Rules And Regulations; Procedures

1. 42 U.S.C. § 405(a)

The Secretary shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this subchapter, which are necessary or appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

B. Administrative Determination Of Entitlement To Benefits; Findings Of Fact; Hearings

1. 42 U.S.C. § 405(b)

(1) The Secretary is directed to make findings of fact, and decisions as to the rights of any individual applying for a payment under this subchapter. Any such decision by the Secretary which involves a determination of disability and which is in whole or in part unfavorable to such individual shall contain a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Secretary's determination and the reason or reasons upon which it is based. Upon request by any such individual or upon request by a wife, divorced wife, widow, surviving divorced wife, surviving divorced mother, surviving divorced father, husband, divorced husband, widower, surviving divorced husband, child, or parent who makes a showing in writing that his or her rights may be prejudiced by any decision the Secretary has rendered, he shall give such applicant and such other indi-

vidual reasonable notice and opportunity for a hearing with respect to such decision, and, if a hearing is held, shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision. Any such request with respect to such a decision must be filed within sixty days after notice of such decision is received by the individual making such request. The Secretary is further authorized, on his own motion, to hold such hearings and to conduct such investigations and other proceedings as he may deem necessary or proper for the administration of this subchapter. In the course of any hearing, investigation, or other proceeding, he may administer oaths and affirmations, examine witnesses, and receive evidence. Evidence may be received at any hearing before the Secretary even though inadmissible under rules of evidence applicable to court procedure.

C. Judicial Review

1. 42 U.S.C. § 405(g)

Any individual, after any final decision of the Secretary made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Secretary may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of his answer the Secretary shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the

cause for a rehearing. The findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Secretary or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Secretary, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Secretary made for good cause shown before he files his answer, remand the case to the Secretary for further action by the Secretary, and it may at any time order additional evidence to be taken before the Secretary, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Secretary shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm his findings of fact or his decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which his action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

II. Title II Claims Adjudication Process Incorporated Into Title XVIII

A. Administrative Determinations

1. 42 U.S.C. § 1395ii

The provisions of sections 406 and 416(j), and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405, shall also apply with respect to this title to the same extent as they are applicable with respect to title II.

2. 42 U.S.C. § 1395ff(a)

The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A or part B, and any other determination with respect to a claim for benefits under part A or a claim for benefits with respect to home health services under part B shall be made by the Secretary in accordance with regulations prescribed by him.

B. Hearings and Judicial Review

1. 42 U.S.C. § 1395ff(b)

(1) Any individual dissatisfied with any determination under subsection (a) as to—

(A) whether he meets the conditions of section 426 of this Act or section 103 of the Social Security Amendments of 1965,

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this title, or section 1395i-2,

(C) the amount of benefits under part A or part B (including a determination where such amount is determined to be zero), or

(D) any other denial (other than under part B of title XI) of a claim for benefits under part A or a claim for benefits with respect to home health services under part

B shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g).

* * * *

(2) Notwithstanding paragraph (1)(C) and (1)(D), in the case of a claim arising—

(A) under part A, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $100 and judicial review shall not be available to the individual under that paragraph if the amount in controversy is less than $1,000; or

(B) under part B, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $500 and judicial review shall not be available to the individual under that paragraph if the aggregate amount in controversy is less than $1,000.

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if the claims involve the delivery of similar or related services to the same individual or involve common issues of law and fact arising from services furnished to two or more individuals.

C. Notice of Determinations

1. 42 U.S.C. § 1395h(j)

An agreement with an agency or organization under this section shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to such agency or organization that is denied, such agency or organization—

(1) furnish the provider and the individual with respect to whom the claim is made with a written explanation of

the denial and of the statutory or regulatory basis for the denial; and

(2) in the case of a request for reconsideration of a denial, promptly notify such individual and the provider of the disposition of such reconsideration.

D. Rights Of Providers To Appeal Denials For Lack Of Medical Necessity

1. 42 U.S.C. § 1395pp(d)

In any case arising under subsection 1395pp(b) (but without regard to whether payments have been made by the individual to the provider or other person) or subsection 1395pp(c), the provider or other person shall have the same rights that an individual has under sections 1395ff(b) and 1395u(b)(3)(C) (as may be applicable) when the amount of benefit or payment is in controversy, except that such rights may, under prescribed regulations, be exercised by such provider or other person only after the Secretary determines that the individual will not exercise such rights under such sections.

III. The Coverage And Waiver Determinations Which The Secretary Must Make Under Title XVIII

A. Coverage Determinations

1. 42 U.S.C. § 1395y(a)(1)

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

B. Waiver Determinations

1. 42 U.S.C. § 1395pp(a)

Where—

(1) a determination is made that, by reason of section 1395y(a)(1) or (9) or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395u(b)(3)(B)(ii), and

(2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B,

then to the extent permitted by this title, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this title), as though section 1395y(a)(1) and section 1395y(a)(9) did not apply and as though the coverage denial described in subsection (g) had not occurred. In each such case the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services. Any provider or other person furnishing items or services for which payment may not be made by reason of section 1395y(a)(1) or (9) or by reason of a coverage denial described in subsection (g) shall be deemed to have knowledge that pay-

ment cannot be made for such items or services if the claim relating to such items or services involves a case, provider or other person furnishing services, procedure, or test, with respect to which such provider or other person has been notified by the Secretary (including notification by a utilization and quality control peer review organization) that a pattern of inappropriate utilization has occurred in the past, and such provider or other person has been allowed a reasonable time to correct such inappropriate utilization.

2. 42 U.S.C. § 1395pp(b)

In any case in which the provisions of paragraphs (1) and (2) of subsection (a) are met, except that such provider or such other person, as the case may be, knew, or could be expected to know, that payment for such services or items could not be made under such part A or part B, then the Secretary shall, upon proper application filed within such time as may be prescribed in regulations, indemnify the individual (referred to in such paragraphs), for any payments received from such individual by such provider or such other person, as the case may be, for such items or services. Any payments made by the Secretary as indemnification shall be deemed to have been made to such provider or such other person, as the case may be, and shall be treated as over payments, recoverable from such provider or such other person, as the case may be, under applicable provisions of law. In each such case the Secretary shall notify such individual of the conditions under which indemnification is made and in the case of comparable situations arising thereafter with respect to such individual, he shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services. No item or service for which an individual is indemnified under this subsection shall be taken into account in applying any limitation on

the amount of items and services for which payment may be made to or on behalf of the individual under this title.

3. 42 U.S.C. § 1395pp(c)

No payments shall be made under this title in any cases in which the provisions of paragraph (1) of subsection (a) are met, but both the individual to whom the items or services were furnished and the provider of service or other person, as the case may be, who furnished the items or services knew, or could reasonably have been expected to know, that payment could not be made for items or services under part A or part B by reason of section 1395y(a)(1) or (a)(9) or by reason of a coverage denial described in subsection (g).

4. 42 U.S.C. § 1395pp(f)(1)

A home health agency which meets the applicable requirements of paragraphs (3) and (4) shall be presumed to meet the requirement of subsection (a)(2).

5. 42 U.S.C. § 1395pp(f)(2)

The presumption of paragraph (1) with respect to specific services may be rebutted by actual or imputed knowledge of the facts described in subsection (a)(2), including any of the following:

(A) Notice by the fiscal intermediary of the fact that payment may not be made under this title with respect to the services.

(B) It is clear and obvious that the provider should have known at the time the services were furnished that they were excluded from coverage.

6. 42 U.S.C. § 1395pp(f)(3)

The requirements of this paragraph are as follows:

(A) The agency complies with requirements of the Secretary under this title respecting timely submittal of bills for payment and medical documentation.

(B) The agency program has reasonable procedures to notify promptly each patient (and the patient's physician)

where it is determined that a patient is being or will be furnished items or services which are excluded from coverage under this title.

7. 42 U.S.C. § 1395pp(f)(4)

(A) The requirement of this paragraph is that, on the basis of bills submitted by a home health agency during the previous quarter, the rate of denial of bills for the agency by reason of a coverage denial described in subsection (g) does not exceed 2.5 percent, computed based on visits for home health services billed.

8. 42 U.S.C. § 1395pp(f)(6)

The Secretary shall monitor the proportion of denied bills submitted by home health agencies for which reconsideration is requested, and shall notify Congress if the proportion of denials reversed upon reconsideration increases significantly.

IV. Recovery of Overpayments Under Title XVIII

A. Payments Regarded As Made To Individual

1. 42 U.S.C. § 1395gg(a)

Any payment under this title to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

B. Recovery From Individual Or Provider

1. 42 U.S.C. § 1395gg(b)(1)-(4)

Where—

(1) more than the correct amount is paid under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that

such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(2) any payment has been made under section 1395f(e) to a provider of services or other person for items or services furnished an individual,

proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments—

(3) to which such individual is entitled under title II of this Act or under the Railroad Retirement Act of 1974, as the case may be, or

(4) if such individual dies before such adjustment has been completed, to which any other individual is entitled under title II of this Act or under the Railroad Retirement Act of 1974, as the case may be, with respect to the wages and self-employment income or the compensation constituting the basis of the benefits of such deceased individual under title II of such Act.

As soon as practicable after any adjustment under paragraph (3) or (4) is determined to be necessary, the Secretary, for purposes of this section, section 1395i(g), and section 1395f(f), shall certify (to the Railroad Retirement Board if the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1974) the amount of the overpayment as to which the adjustment is to be made. For purposes of clause (B) of paragraph (1), such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination that more than such correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid; except that the Secretary may reduce such

three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

2. 42 U.S.C. § 1395gg(c)

There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1395f(e) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1395y(a) and (B) if the Secretary's determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

REGULATORY PROVISIONS

I. The Claims Adjudication Process Under Title II

A. The Process

1. Explanation Of The Administrative Review Process

20 C.F.R. § 404.900(a)

This subpart explains the procedures we follow in determining your rights under title II of the Social Security

Act. The regulations describe the process of administrative review and explain your right to judicial review after you have taken all the necessary administrative steps. These procedures apply also to persons claiming certain benefits under title XVIII of the Act (Medicare); see 42 C.F.R. § 405.701(c). The administrative review process consists of several steps, which usually must be requested within certain time periods and in the following order:

2. Initial Determination

20 C.F.R. § 404.900(a)(1)

This is a determination we make about your entitlement or your continuing entitlement to benefits or about any other matter, as discussed in § 404.902, that gives you a right to further review.

3. Reconsideration

20 C.F.R. § 404.900(a)(2)

If you are dissatisfied with an initial determination, you may ask us to reconsider it.

4. Hearing Before An Administrative Law Judge

20 C.F.R. § 404.900(a)(3)

If you are dissatisfied with the reconsideration determination, you may request a hearing before an administrative law judge.

5. Appeals Council Review

20 C.F.R. § 404.900(a)(4)

If you are dissatisfied with the decision of the administrative law judge, you may request that the Appeals Council review the decision.

6. Federal Court Review

20 C.F.R. § 404.900(a)(5)

When you have completed the steps of the administrative review process listed in paragraphs (a)(1) through

(a)(4) of this section, we will have made our final decision. If you are dissatisfied with our final decision, you may request judicial review by filing an action in a Federal district court.

B. Notice Of Initial Determination

1. 20 C.F.R. § 404.904

We shall mail a written notice of the initial determination to you at your last known address. The reasons for the initial determination and the effect of the initial determination will be stated in the notice. The notice also informs you of the right to a reconsideration. We will not mail a notice if the beneficiary's entitlement to benefits has ended because of his or her death.

C. Effect Of Initial Determinations

1. 20 C.F.R. § 404.905

An initial determination is binding unless you request a reconsideration within the stated time period, or we revise the initial determination.

D. Reconsideration

1. 20 C.F.R. § 404.907

Reconsideration is the first step in the administrative review process that we provide if you are dissatisfied with the initial determination. If you are dissatisfied with our reconsidered determination, you may request a hearing before an administrative law judge.

E. Administrative Hearing

1. 20 C.F.R. § 404.929

If you are dissatisfied with one of the determinations or decisions listed in § 404.930 you may request a hearing. The Associate Commissioner for Hearings and Appeals, or his or her delegate, shall appoint an administrative law judge to conduct the hearing. If circumstances warrant,

the Associate Commissioner, or his or her delegate, may assign your case to another administrative law judge. At the hearing you may appear in person, submit new evidence, examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she shall issue a decision based on the hearing record. If you waive your right to appear at the hearing, the administrative law judge will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration. .

F. Appeals Council Review

1. 20 C.F.R. § 404.967

If you or any other party is dissatisfied with the hearing decision or with the dismissal of a hearing request, you may request that the Appeals Council review that action. The Appeals Council may deny or dismiss the request for review, or it may grant the request and either issue a decision or remand the case to an administrative law judge. The Appeals Council shall notify the parties at their last known address of the action it takes.

G. Reopenings And Revisions

1. General

20 C.F.R. § 404.987(a)

Generally, if you are dissatisfied with a determination or decision made in the administrative review process, but do not request further review within the stated time period, you lose your right to further review. However, a determination or a decision made in your case may be reopened and revised. After we reopen your case, we may revise the earlier determination or decision.

2. Procedure For Reopening And Revision

20 C.F.R. § 404.987(b)

You may ask that a determination or a decision to which you were a party be revised. The conditions under which we will reopen a previous determination or decision are explained in § 404.988.

3. Good Cause

20 C.F.R. § 404.989(a)(1), (2) and (3)

We will find that there is good cause to reopen a determination or decision if—

(1) New and material evidence is furnished;

(2) A clerical error in the computation or recomputation of benefits was made; or

(3) The evidence that was considered in making the determination or decision clearly shows on its face that an error was made.

20 C.F.R. § 404.989(b)

We will not find good cause to reopen your case if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the determination or decision was made.

II. The Claims Adjudication Process Under Title XVIII

A. General

1. 42 C.F.R. § 405.701(a)

This subpart implements 42 U.S.C. § 1395ff. Section 1395ff provides that the Secretary will make determinations about the following matters, and section 1395ff(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to:

(1) Whether the individual is entitled to hospital insurance (Part A) or supplementary medical insurance (Part B) under title XVIII of the Act; or

(2) The amount payable under hospital insurance.

B. The Process

1. Determinations

42 C.F.R. § 405.701(b)

This subpart establishes the procedures governing initial determinations, reconsidered determinations, hearings, and final agency review, and the reopening of determinations and decisions that are applicable to matters arising under paragraph (a) of this section.

2. Title II Process Incorporated

42 C.F.R. § 405.701(c)

Subparts J and R of 20 C.F.R. Part 404 (dealing with determinations, the administrative review process and representation of parties) are also applicable to matters arising under paragraph (a) of this section, except to the extent that specific provisions are contained in this subpart.

3. Notice

42 C.F.R. § 405.702

After a request for payment under part A of title XVIII of the Act is filed with the intermediary by or on behalf of the individual who received inpatient hospital services, extended care services, or home health services, and the intermediary has ascertained whether the items and services furnished are covered under part A of title XVIII, and where appropriate, ascertained and made payment of amounts due or has ascertained that no payments were due, the individual will be notified in writing of the initial determination in his case. In addition, if the items or services furnished such individual are not covered under

part A of title XVIII by reason of § 411.15(g) or § 411.15(k) and payment may not be made for such items or services under § 411.400 only because the requirements of § 411.400(a)(2) are not met, the provider of services which furnished such items or services will be notified in writing of the initial determination in such individual's case. These notices shall be mailed to the individual and the provider of services at their last known addresses and shall state in detail the basis for the determination. Such written notices shall also inform the individual and the provider of services of their right to reconsideration of the determination if they are dissatisfied with the determination.

4. Requests For Payment By Or On Behalf Of Individuals

42 C.F.R. § 405.704(b)

An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under part A of Medicare, including a determination with respect to:

(1) The coverage of items and services furnished;

* * * *

(11) The medical necessity of services;

(12) When services are excluded from coverage as custodial care or as not reasonable and necessary, whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage;

(13) Any other issues having a present or potential effect on the amount of benefits to be paid under part A of Medicare, including a determination as to whether there has been an overpayment or underpayment of benefits paid under part A, and if so, the amount thereof; and

(14) Whether a waiver of adjustment or recovery under sections 1395gg(b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1395f(e) of the Act) has been made with respect to an individual.

5. Initial Determination With Respect To A Provider Of Services

42 C.F.R. § 405.704(c)

An initial determination with respect to a provider of services shall be a determination made on the basis of a request for payment filed by the provider under part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

(1) A finding by the intermediary that such items or services are not covered by reason of § 411.15(g) or § 411.15(k); and

(2) A finding by the intermediary that either such individual or such provider of services, or both, knew or could reasonably have been expected to know that such items or services were excluded from coverage under the program.

6. Effect Of Initial Determinations

42 C.F.R. § 405.708(a)

The initial determination under § 405.704(a) or (b) shall be final and binding upon the individual on whose behalf payment under part A has been requested or, if such individual is deceased, upon the representative of such individual's estate, unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such individual (or the representative of such individual's estate if the individual is deceased) shall be the party to such initial determination.

42 C.F.R. § 405.708(b)

The initial determination under § 405.704(c) shall be final and binding upon the provider of services unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such provider of services shall be the party to such initial determination.

7. Reconsideration

42 C.F.R. § 405.710(a)

An individual who is a party to an initial determination, as specified in § 405.704(a) and (b), (or if such individual is deceased, the representative of such individual's estate) and who is dissatisfied with the initial determination may request a reconsideration of such determination in accordance with § 405.711 regardless of the amount in controversy.

8. Reconsideration

42 C.F.R. § 405.710(b)

A provider of services who is a party to an initial determination (as specified in § 405.704(c) and who is dissatisfied with such initial determination may request a reconsideration of such determination in accordance with § 405.711, regardless of the amount in controversy, but only if the individual on whose behalf the request for payment was made has indicated in writing that he does not intend to request reconsideration of the intermediary's initial determination on such request for payment, or if the intermediary has made a finding (see § 405.704(c)) that such individual did not know or could not reasonably have been expected to know that the expenses incurred for the items or services for which such request for payment was made were not reimbursable by reason of § 411.15(g) or § 411.15(k).

42 C.F.R. § 405.715(a)

In reconsidering an initial determination, the Health Care Financing Administration shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the Social Security Administration or the Health Care Financing Administration or otherwise obtained by the intermediary or the Health Care Financing Administration; and shall make a determination affirming or revising, in whole or in part, such initial determination.

42 C.F.R. § 405.715(b)

If the request for reconsideration is filed by an individual with respect to an initial determination specified in § 405.704(b)(12), the provider of services who furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto. If pursuant to § 405.710(b) a request for reconsideration is filed by a provider of services with respect to an individual determination under § 405.704(c), the individual who was furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto.

42 C.F.R. § 405.716

Written notice of the reconsidered determination shall be mailed by the Health Care Financing Administration to the parties and their representatives at their last known addresses. Such notice shall state the specific reasons for the reconsidered determination and shall advise the parties of their right to a hearing if the amount in controversy is $100 or more, or, if appropriate, advise them of the requirements for use of the expedited appeals process (see § 405.718).

9. Hearing

42 C.F.R. § 405.720(a)-(d)

A person has a right to a hearing regarding any initial determination made under § 405.704 if:

(a) Such initial determination has been reconsidered by the Health Care Financing Administration;

(b) Such person was a party to the reconsidered determination;

(c) Such person or his representative has filed a written request for a hearing in accordance with the procedure described in § 405.722; and

(d) The amount in controversy is $100 or more.

10. Appeals Council Review

42 C.F.R. § 405.724

Appeals Council review is provided by 20 C.F.R. § 404.967.

11. Determining Amount in Controversy

42 C.F.R. § 405.740(a)

The following principles shall be applicable for purposes of determining the amount in controversy:

(a) The amount in controversy should be computed as the actual amount charged the individual for the items and services in question less deductible and coinsurance amounts applicable in the particular case.

42 C.F.R. § 405.740(c)

Where the issues in dispute relate to services furnished to a patient of a provider of services, all items or services in dispute arising from a single continuous period of treatment shall be considered in determining the amount in controversy.

42 C.F.R. § 405.740(d)

The principle set forth in paragraph (c) of this section shall be applicable even when more than one request for payment is submitted, and notice of utilization issued, because of the provider's billing practices.

42 C.F.R. § 405.740(e)

Any series of posthospital home health visits shall be considered collectively in determining the amount in controversy.

20 C.F.R. § 405.740(f)(1) and (2)

Appeals from determinations pertaining to inpatient hospital services, extended care services or posthospital home health services shall not ordinarily be additive for purposes of determining the amount in controversy except, where:

(1) The denial of payment of inpatient hospital services prevents the individual from meeting a condition precedent for payment for extended care or home health services; or

(2) The same factor is at issue in more than one claim for benefits by such individual (*e.g.*, an individual, during June, is hospitalized twice; in each case the claim for payment is denied on the basis that the hospitalization occurred during an ongoing spell of illness which began prior to June and in which the individual had already utilized all available benefit days; the individual appeals claiming that he was in a new spell of illness and had the full number of benefit days available).

12. Reopening and Revision

42 C.F.R. § 405.750(a)

Reopenings concerning applications and entitlement. A determination, or decision, or revised determination or decision made by the Social Security Administration concerning any matter under § 405.704(a), may be reopened and revised under 20 C.F.R. § 404.988 (Conditions for reopening).

42 C.F.R. § 405.750(b)

Reopenings concerning a request for payment. An initial, revised, or reconsidered determination of the Health Care Financing Administration, or a decision or revised decision of a presiding officer or of the Appeals Council, with respect to an individual's rights concerning a request for payment under Part A of Medicare, which is otherwise final under 20 C.F.R. § 404.955 or 404.981 and 405.708, or 405.717 of this subpart may be reopened:

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 C.F.R. § 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

APPENDIX B

Decision *In the Matter of Albuquerque Visiting* Nursing Service, Inc. (September 29, 1986) Page 13 of Decision, Joint Appendix at 60

Turning to the merits of the sampling issue, the Administrative Law Judge acknowledges that HCFA Rulings are ordinarily binding on him, within the terms of 42 C.F.R. Section 401.108(c). Still, he disputes the binding effect of Ruling No. HCFAR-86-1 in the instant case. As outlined in the letter of April 8, 1986, sent by counsel for AVNS: the ruling was not published in the Federal Register prior to issuance, as required by 5 U.S.C. Section 553 (and also by 5 U.S.C. Section 552(a)(1)(D)), which mandates such publication in the case of substantive policies; the ruling went into effect on February 20, 1986 and has not been expressly declared to have retroactive application; and a prehearing order disposing of the sampling question had already been issued with respect to AVNS well before February 20, 1986.

It should be stressed that, under 5 U.S.C. Section 552(a)(1), AVNS may not be adversely affected in any manner by a ruling required to be published in the Federal Register and not so published, except to the extent that the agency had actual and timely notice of the terms thereof. *See Los Alamitos General Hospital, Inc. v. Donnelly*, 558 F. Supp. 1141 (D.D.C. 1983); *St. John's Hickey Memorial Hospital, Inc. v. Califano*, 599 F.2d 803 (7th Cir. 1979); *Hooper v. Harris*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 34,619 (D. Conn. No. H-80-99 (M.J.B.), May 1, 1985); *Kron v. Schweiker*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 32,136 (E.D. La. No. 80-1332, Aug. 23, 1982); *Schupak M.D. d/b/a/ Queens Artificial Kidney Center v. Mathews*, Medicare and Medicaid Guide (CCH), New Developments 27,987 (D.D.C. Civ. No. 75-1109, Sept. 17, 1976); *Christian Hospital of St. Louis v. Califano*, Medi-

care and Medicaid Guide (CCH) New Developments Paragraph 28,968 (E.D. Mo. No. 76-1176-C(2), Feb. 28, 1978). It is hard to grasp how AVNS could possibly have had timely notice of Ruling HCFAR-86-1, given that notice was not received in sufficient time to enable the agency to participate in the rule-making process or to change its own policies and procedures to avoid any adverse impact from the ruling. Indeed, the rule-making provisions of the A.P.A. may not be avoided by the process of making rules in the course of an adjudicatory proceeding. *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 89 S. Ct. 1426, 22 L.Ed.2d 709 (1969).

Moreover, counsel for AVNS voiced a valid concern in his letter of April 8, 1986 about the propriety, under 5 U.S.C. Section 554(d), of applying Ruling HCFAR-86-1 to the instant Administrative Law Judge proceeding, when the rule gives every appearance of having been issued to invest with binding authority arguments which had previously been fully considered and rejected in that proceeding by the Administrative Law Judge.

Furthermore, HCFA Rulings which conflict with the Social Security Act or with regulations promulgated thereto are invalid. *See, e.g., Tucson Medical Center v. Heckler*, 611 F. Supp. 823 (D.D.C. 1985); *St. Francis Hospital v. Heckler*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 34,918 (S.D. W. Va. No. 84-2318, Sept. 30, 1985). For, the authority of an administrative agency to make rules is not the power to make law. *See, e.g., Dixon v. United States*, 381 U.S. 68, 85 S. Ct. 1301, 14 L.Ed.2d 811 (1965). The question therefore arises whether Ruling No. HCFAR-86-1 poses a conflict with the Social Security Act or pertinent regulations.

It is evident that a conflict would exist if HCFA issued a ruling expressly and directly abrogating a provider's otherwise-existing statutory or regulatory rights to limitation of liability, to notice of initial determinations, or to ad-

ministrative or court review. What cannot be done directly cannot be done by indirection, either. *See, e.g., Anderson v. Martin*, 375 U.S. 399, 84 S. Ct. 454, 11 L.Ed.2d 430 (1964).[1] In other words, if the provider's rights to limitation of liability, notice of initial determinations, and/or review thereof apply with respect to *each separate case*, HCFA cannot foreclose invocation of those rights with respect to claims outside the sample by the simple expedient of declaring an overpayment on some proportion of those claims without first reviewing them.

Of course, the position of HCFA is that the Act and regulations afford those rights to providers only with respect to a representative sample of claims where administrative convenience warrants use of such a sample. The arguments in support of that position, as elaborated in Ruling No. HCFAR-86-1, are not persuasive.[2]

First, while the right of the government to recover monies illegally or erroneously paid out under Part A of the Medicare Program is not questioned (*Cf.* Ruling, at 4-6), and while it may well be true that "the existence of appropriate remedies to enforce that right will be presumed in the absence of a clear indication of a contrary congressional intent" (*Id.* at 6), the language of the Social Security Act is itself an indicator of congressional intent and is not

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[1] Although the aforementioned case pertains to a statutory enactment in violation of the Constitution, the principle would seem to be equally applicable to rules in conflict with statutory or regulatory provisions.

[2] Although this case is not precisely on point, as it does not involve sampling to project a Medicare Part A overpayment, counsel for AVNS, in his letter of June 12, 1986, cited *Fox v. Bowen*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 35,374 (D. Conn. N. 78-541 (JAC), Apr. 23, 1986), as authority for the proposition that Medicare Part A coverage determinations must be made on an individualized basis and not on the basis of arbitrary presumptions or rules of thumb.

to be ignored. Indeed, the courts look first to the statutory language to discern the intent of Congress, and only then to the legislative history if the statutory language is unclear. *See, e.g., Blum v. Stenson*, 465 U.S. 886, 104 S. Ct. 1541, 79 L.Ed.2d 891 (1984). The plain language of 42 U.S.C. Section 1395pp(d) establishes the congressional intent against use of sampling as a remedy for the government in Part A Medicare overpayment matters.

The statutory provision reads: "*In any case* arising under Subsection (b) of this Section . . . or Subsection (c) of this Section, the provider . . . shall have *the same rights* that an individual has under Section 1395ff(b) of this title. . . ." (Emphasis added). Since an individual has a right to a hearing under Section 1395ff(b) to the same extent as is provided for in 42 U.S.C. Section 405(b) on *any* determination he is dissatisfied with regarding the amount of benefits payable under Part A (including a determination that the amount payable is zero), and since that individual also has a right to judicial review of the Secretary's final decision under 42 U.S.C. Section 405(g), so long as he meets the respective amount in controversy requirements, a provider must likewise have those rights with respect to *any* amount of benefits determination covered by Section 1395ff(b) or (c), so long as the respective amount in controversy requirements are met (and the Secretary finds that the individual affected by the determination will not exercise his own review rights).[3] Obviously, then, Section 1395pp(d) affords review rights with respect to each separate adverse qualifying determination under Sections 1395pp(b) and (c).

By the same token, as counsel for AVNS convincingly demonstrates in his pre-hearing memorandum of April 5, 1985 (at 14-15), the notice requirements spelled out in

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[3] Incidentally, a reading of Section 1395pp discloses that the terms "case" and "determination" are used interchangeably.

Sections 1395pp(a) and (b), pertaining to limitation on liability and indemnification of an individual, and the notice requirements of 42 C.F.R. Section 405.702, pertaining to initial determinations, preclude the denial of unspecified claims for services furnished to unspecified individuals. Yet, the use of sampling, by its very nature, entails such denials.

HCFA argues, in its ruling No. HCFAR-86-1 (at 5), that the courts have recognized extrapolation based on a sample as a permissible auditing method in cases arising under the Social Security Act. However, two of the cases cited in the ruling in support of that proposition—*New Jersey Welfare Rights Organization v. Cahill*, 349 F. Supp. 501 (D. N.J. 1972), and *Rosado v. Wyman*, 322 F. Supp. 1173 (E.D. N.Y. 1970), *aff'd*, 402 U.S. 991 (1971)—concerned calculation of the standard of need for AFDC purposes. Those cases are not even remotely related to the present controversy. The other two cases cited in its ruling by HCFA—*Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982), and *State of Georgia v. Califano*, 446 F. Supp. 404 (N.D. Ga. 1977)—concerned Medicaid reimbursement and not assessment of an overpayment under Medicare Part A. In addition, the *Illinois Physicians Union* case involved an express authorization of sampling under Illinois Medicaid regulations (*See* 675 F.2d, at 153); and in the *State of Georgia* case, Georgia did not argue that sampling conflicted with federal law (*Cf.* 446 F. Supp., at 406.409) and did not challenge use of sampling at any point in the administrative proceedings. (*Cf.* 446 F. Supp., at 410).[4]

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[4] Two other cases—*Mt. Sinai Medical Center v. Weinberger*, 522 F.2d 179 (5th Cir. 1975) and *Daytona Beach General Hospital v. Weinberger*, 435 F. Supp. 891 (M.D. Fla. 1977)—have also been cited by government counsel in support of sampling to determine overpayments under Medicare Part A. (See Prehearing Brief for the Health Care Financing Administration,

HCFA further argues (*see* Ruling, at 8-9) that use of sampling to calculate overpayments does not prevent providers from exercising their rights under state law to bill individuals outside the sample for items or services these individuals knew or should have known were not due them. For, a provider could supposedly request from the Intermediary or the Peer Review Organization (P.R.O.) a list of individuals outside the sample who were notified at some earlier date that they had received noncovered services of some sort. This avenue of redress is generally of little avail absent identification of the individuals outside the sample whose audited claims have been denied and absent identification of the particular items or services outside the sample being rejected. The mere fact that a person was at one time informed that the services rendered them were neither reasonable nor necessary for diagnosis or treatment of an illness or injury does not necessarily mean that subsequent services, even for the same general illness or injury, are also noncovered. AVNS cannot attempt to bill individuals named by a P.R.O. or an intermediary without incurring considerable risk. For, under 42 U.S.C. Section 1395cc(a)(2)(A), a provider of services must agree not to charge any individual for covered services (except as allowed in 42 U.S.C. Section 1395cc(a)(2), pertaining to deductibles, coinsurance amounts, etc.)

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dated April 8, 1985, at 7-8). However, as counsel for AVNS argued in his pre-hearing memorandum of April 5, 1985, at 24-29, both the *Mt. Sinai* and *Daytona Beach* cases arose prior to the enactment of 42 U.S.C. Section 1395pp. Also, the Court of Appeals in the *Mt. Sinai* case simply held that the government's common law right to recoup overpayments had not been abolished. The validity of sampling to calculate overpayment was not decided by the Court of Appeals—or, for that matter, by the District Court in its initial decision or upon remand. Finally, the *Daytona Beach* case only addressed the validity of the sample size and not of sampling, itself.

Allowing the possibility that a provider might be effectively barred from charging a beneficiary for noncovered services in at least some instances, HCFA then argues (at pp. 9-10 of the ruling) that public policy considerations favor the government's recovery of overpayments over the provider's billing interest and the government's ease in processing over the provider's stake in case-by-case auditing. The language of the ruling even suggests that a provider's objection to the use of sampling is nothing more than a bad faith attempt on the part of the provider to retain payments to which it was never legally entitled.

Still, as recognized in *Stanley v. Illinois*, 405 U.S. 645, at 657, 92 S. Ct. 1208, at 1215, 31 L.Ed. 551, at 561 (1972), there are "higher values than speed and efficiency." The undersigned Administrative Law Judge does not attempt to resolve the due process issue raised by the government's irrebuttable presumption of an overpayment for the larger universe of claims so long as any overpayment is upheld for a valid sample of claims.[5] Even so, it cannot reasonably be assumed that Congress was unmindful of the extra burden placed on HCFA and its intermediaries by 42 U.S.C. Section 1395pp, which gives providers a right to review of Medicare Part A coverage determinations. Having failed to expressly authorize sampling in the calculation of overpayments under Part A, and having expressly conferred upon providers statutory rights with respect to coverage questions which are only consistent with case-by-case consideration, Congress has itself placed those rights higher in the scale of values than the government's administrative convenience.

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[5] The due process issue in the instant case is different than that involved in *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982), or in *State of Georgia v. Califano*, 446 F. Supp. 404 (N.D. Ga. 1977), in which Illinois physicians and the State of Georgia would have been permitted to rebut the presumed overpayment by conducting a 100% audit, albeit at their own expense.

The recommended conclusions of the Administrative Law Judge are that Ruling No. HCFAR-86-1, which is in conflict with the Act and regulations, is without force and effect as to the instant case and that the Act and regulations prohibit sampling to extrapolate an overpayment against AVNS under Medicare Part A.

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Should the Appeals Council decide that sampling to project an overpayment against Albuquerque Visiting Nursing Service, Inc., is permitted under the Social Security Act and regulations promulgated thereto, the Administrative Law Judge recommends, pursuant to a request for the same by counsel for Albuquerque Visiting Nursing Service, Inc., in his letter of April 8, 1986, that the matter be remanded to an Administrative Law Judge for a supplemental hearing regarding the exact manner in which sampled cases were selected, the nature of the proprietary computer program allegedly used, and any other issues bearing on the sampling techniques which were employed and their validity.

APPENDIX C
(ADDENDUM II FROM PLAINTIFFS-APPELLANTS' BRIEF IN THE COURT OF APPEALS)

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 23, 1987

The Honorable Charles A. Bowsher
Comptroller General of the
United States
Washington, D.C. 20548

Dear Mr. Bowsher:

In accordance with the requirements of OMB Circular A-50, I am enclosing the Department's comments on the U.S. General Accounting Office's Report, "Medicare: Need to Strengthen Home Health Care Payment Controls and Address Unmet Needs," GAO/HRD-87-9 dated December 1986.

Sincerely,

/s/ Otis R. Bowen, M.D.
Secretary

Enclosure

Excerpt (page 4) of Department of Health and Human Services, Comments on the General Accounting Office Final Report, Need to Strengthen Home Health Care Payment Controls and Address Unmet Needs

Recommendation

That the Secretary of HHS direct the Administrator of HCFA to revise the home health postpayment utilization review program guidance to require intermediaries to use statistically valid sampling techniques for identifying and projecting the amount of noncovered care to the universe of claims paid.

Department Comment

We do not agree with this recommendation. Unlike Part B physicians claims which GAO cites as a precedent for projecting overpayments, home health agencies have certain rights which would not be available under this procedure since only sample cases are specifically identified.

Under section 1879 of the Social Security Act, payment is made for services determined to be noncovered when both the beneficiary and provider did not know or could not be reasonably expected to know that payment would not be made. The Omnibus Budget Reconciliation Act of 1981 extends this provision to services that were not formerly covered and also extends "favorable presumption" (*i.e.*, provider is deemed not to know if denial rate is below a certain percentage) to providers for these services. It would appear that there is congressional interest in protecting the providers' rights.

Under Part B, the criteria for selection for postpayment review are aberrant patterns identified through a physician profiling system. This system provides factual evidence that a physician is providing more or different services from his peers. The home health selection is based on criteria that provide no factual evidence that the providers selected

for review provide more noncovered services than other providers. In fact, existing reports support a thesis that billing of noncovered services is not limited to certain providers.

HCFA will be working closely with the home health industry to improve knowledge of Medicare coverage. Current medical review activities will be used to identify providers needing more intensive review and areas requiring more intensive provider education.

APPENDIX D
(JOINT APPENDIX 366-67)

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
SOCIAL SECURITY ADMINISTRATION
OFFICE OF HEARINGS AND APPEALS

ORDER OF APPEALS COUNCIL
DISMISSING REQUEST FOR HEARING

In case of	Claim for
Albuquerque Visiting Nursing Service Claimant	Health Insurance Benefits
Henry Roeder (Beneficiary)	472-05-6353 (Social Security Number)

This case is before the Appeals Council following receipt of a recommended decision dated September 29, 1986.

At issue is whether the Health Care Financing Administration may determine that the provider, Albuquerque Visiting Nursing Service, has been overpaid based on review of a sampling of cases. Health Care Financing Administration Ruling 86-1 directs the Social Security Administration to apply statistical sampling to project an overpayment to a provider when claims reflect that the provider has demonstrated a pattern of erroneous billing or over utilization, and when a case by case review is not administratively feasible (42 CFR 401.108). Appeals of coverage determinations may be made, but only on individually identifiable claims.

Section 405.720(d) of Regulations No. 5 (42 CFR 405.702(d)) provides that there is no right to a hearing unless the amount in controversy equals or exceeds $100.00. The amount in controversy is defined as the amount charged

the individual for the items and services in question (section 405.740, (20 CFR 405.740)). It is ascertained after the reconsidered determination. For services rendered prior to January 1, 1987, there was no provision for aggregation of the claims of two or more individuals, nor is there a regulatory provision that permits magnification of the overpayment amount in an individual case in proportion to the ratio of the total individual overpayments to the overpayment assessed against the provider.

In view of the above, the amount in controversy in this case is determined to be $44.00. The claimant's request for hearing on this case should be dismissed under the provisions of section 405.747 (42 CFR 405.747).
Accordingly, pursuant to its authority under 20 CFR 404.967, the Appeals Council hereby dismisses the request for hearing filed on October 12, 1984. The determination dated September 24, 1984, stands as the final decision of the Secretary.

Notice of this action is hereby given by mailing a copy to the provider and to the representative.

Appeals Council

/ /s/ /
Larry K. Banks, Member

/ /s/ /
Burton Berkley, Member

Date: April 4, 1988

cc:
Mrs. Muriel R. James
Executive Director
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APPENDIX E
(JOINT APPENDIX 13)

HCFA RULINGS

Department of Health and Human Services

Health Care Financing Administration

Ruling No. HCFAR-86-1 Date: 2/20/86

USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENT TO MEDICARE PROVIDERS AND SUPPLIERS

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex statutes or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, HCFA contractors, the Provider Reimbursement Review Board, and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This ruling, HCFAR 86-1, is the first to be issued in a format separate from the bound *HCFA Rulings* booklet or a *Federal Register* notice. HCFA is currently in the process of transferring all *HCFA Rulings* that have been issued into a looseleaf booklet form. This ruling, which is effective on the date of issuance, will be incorporated into that looseleaf booklet.

(4)

No. 91-674

IN THE

Supreme Court Of The United States

OCTOBER TERM, 1991

Chaves County Home Health Service, Inc., Albuquerque Visiting Nurse Service, Inc., and Bayonne Visiting Nurse Association, Inc.,

Petitioners,

v.

Louis W. Sullivan, M.D.,
Secretary of Health and Human Services,

Respondent.

BRIEF OF AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMICI CURIAE:
National Association of Rehabilitation Agencies
American Physical Therapy Association
American Occupational Therapy Association
American Medical Association
American Speech-Language Hearing Association
Private Practice Section of the American Physical Therapy Association

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No. 91-674

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BRIEF OF AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

This brief *amici curiae* in support of the Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit is submitted by the National Association of Rehabilitation Agencies ("NARA"), American Physical Therapy Association ("APTA"), American Occupational Therapy Association ("AOTA"), American Medical Association ("AMA"), American Speech-Language Hearing Association ("ASHA"), and the Private Practice Section of the American Physical Therapy Association ("PPS")(hereinafter collectively "*Amici*"). For the reasons set out herein, in the Petition for Writ of Certiorari, as well as in the Brief of *Amici Curiae* submitted by the American Hospital Association, American Association of Homes for the Aging, American Federation of Home Health Agencies, and the Home Health Services and Staffing Association, these *Amici* respectfully

request this Court to grant the petition for a writ of certiorari so that the lawfulness of the Secretary of Health and Human Services' ("Secretary") sample adjudication scheme may be reviewed.

I. INTEREST OF AMICI CURIAE

The *Amici* are six national professional associations representing tens of thousands of health care providers which furnish medical services to millions of Medicare beneficiaries.[1] Members of these organizations are "providers" or "suppliers" of services under the Medicare program (42 U.S.C. § 1395x(u)) whose services are paid for principally under Part B of Medicare, although members of these associations render some services which may be covered by Part A. The *Amici* are convinced that the Secretary's use of sample adjudication will cause serious harm to Part B providers, beneficiaries of Part B care, and the Medicare program itself.

NARA, a not-for-profit corporation organized under the laws of the State of Wisconsin, represents approximately 200 Medicare-certified rehabilitation agencies nationwide. Rehabilitation agencies provide their patients with integrated multi-disciplinary rehabilitative services including physical therapy, speech-language pathology, occupational therapy, and social or vocational adjustment services. Many of the services furnished by rehabilitation agencies are rendered to Medicare beneficiaries for which payment is made by the Medicare program.

APTA, an Illinois corporation, is a non-profit association composed of licensed physical therapists, physical therapist assistants, and students of physical therapy. APTA has over 51,000 members and represents approximately 60% of all licensed physical therapists in the United States. As such, APTA is the largest organization of these health professionals

[1] The consents of all the parties to the filing of this brief have been filed with the Court.

in the country and is the recognized spokesman for their interests. Medicare beneficiaries are frequent users of services furnished by members of APTA and Medicare covers the costs of such care.

ASHA is a Kansas non-profit corporation which represents approximately 75% of the speech-language pathologists and audiologists in the country. With over 65,000 members, ASHA is the nationally-recognized advocate for the interests of these professionals. Speech-language pathology and audiology services furnished to Medicare beneficiaries are covered and paid for by Medicare.

AOTA is a District of Columbia non-profit corporation which represents the professional interests of over 44,000 occupational therapists, occupational therapist assistants, and students of occupational therapy. Occupational therapy services are covered under the Medicare program and AOTA members provide services to program beneficiaries in a variety of delivery settings.

AMA is a private, voluntary, non-profit organization of physicians. The AMA was founded in 1846 to promote the science and the art of medicine and improve the public health. Its 280,000 members – over half of all physicians currently licensed to practice medicine – practice in all fields of medical specialization.

PPS, organized in 1956, represents over 5,000 physical therapists who pursue their profession in private practice instead of in hospitals, rehabilitation centers, nursing homes, or similar institutional settings. The PPS also represents physical therapy students, educators, researchers, physical therapist assistants, and administrative assistants. PPS represents private practice physical therapists before governmental agencies, professional and voluntary associations, and numerous public forums.

The *Amici* vigorously support the petition for a writ of certiorari because the Secretary's use of statistical sampling methodologies to adjudicate Medicare claims will carry the following dire consequences:

First, sampling will likely cause severe financial hardship to, and perhaps the insolvency of, any provider against whom the technique is used. The pernicious consequences of statistical sampling are evident from the undisputed facts in the case before the Court. On the basis of extremely small samples of claims, the Secretary demanded repayment of $138,113.38 from Albuquerque Visiting Nurse Service, Inc., $46,913.19 from Chaves County Home Health Service, Inc., and $1,506,639.00 from Bayonne Visiting Nurse Association, Inc. The Secretary's repayment demands forced Albuquerque VNS into bankruptcy and nearly led to the insolvency of Bayonne VNA as well. In another case, a Medicare-certified rehabilitation agency was forced to close its doors as a result of the Secretary's use of statistical sampling. *See Mile High Physical Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988).

The *Amici* respectfully submit that if the use of statistical sampling is upheld, the financial demise of numerous Medicare Part B (and Part A) providers and suppliers will be ordained.

Second, at a time when the aged population is expanding rapidly and the demand for Medicare services is growing at an unprecedented rate, statistical sampling will deter providers from participating in the Medicare program and impair the ability of existing providers to furnish services to Medicare beneficiaries. Statistical sampling significantly increases the business risk associated with entering into a provider participation agreement with the Secretary because even small, good faith errors on claims submitted for payment can result in huge repayment demands. The risk, of course, is heightened as Medicare carriers and intermediaries become more scrupulous

in their claims review in the face of mounting budget deficit pressures to reduce Medicare program costs.

Third, as explained more fully below, statistical sampling deprives providers and beneficiaries of their rights to individualized claims review. *See infra* at 13-15. The absence of individual determinations harms providers because they have no opportunity to defend themselves through the use of medical records and expert testimony on claims not included in the sample. In addition, individual claims determinations furnish providers with a constant source of information about subtle, yet important, shifts in the types of claims which intermediaries and carriers will pay as well as the documentation they require to support payment of a claim. Statistical sampling subverts this dialogue and makes it far more difficult for providers to respond in a timely fashion to changes in a carrier or fiscal intermediary's coverage interpretations or documentation requirements.

Fourth, faced with the prospect of an enormous repayment demand resulting from statistical sampling, providers will refrain from providing care or entering into a course of treatment with a patient where there is even the slightest question whether Medicare will cover it. Sampling, therefore, forces providers to alter their methods of practice and treatment patterns even for services which are legitimate and needed by the beneficiary. As a result, Medicare beneficiaries will have significantly reduced access to health care services which they require.

Fifth, sampling prevents providers from collecting payments due from beneficiaries for services not covered by Medicare. *See infra* at 15. Under the law, providers have the right to collect payment from beneficiaries where Medicare has declined to pay for the service. Fundamental to a provider's ability to collect such payment is the identification of the beneficiary whose claim was denied as well as the reasons for the denial. Because, by definition, sampling does not identify the beneficiary or the reasons for the denial for any claim not

included in the sample – *i.e.*, the majority of denied claims – the provider has no way of exercising its right of recourse against the beneficiary. Sampling, therefore, is a "double-whammy" for providers. On one hand, it inevitably results in huge repayment demands. On the other, it precludes providers from offsetting those losses by collecting funds lawfully due them from beneficiaries.

II. SUMMARY OF ARGUMENT

The *Amici* urge this Court to grant the petition for writ of certiorari and ultimately hold that the use of statistical sampling to readjudicate Medicare coverage determinations is unlawful. Sample adjudication causes grievous financial injury to Medicare providers, deters them from providing needed care to Medicare beneficiaries, and precludes providers from collecting payments due from beneficiaries for services which Medicare has determined that it will not cover.

The Court should review the Court of Appeals' decision because it directly contravenes specific statutory and regulatory mandates under Part B and Part A of Medicare for individualized claims review, notice of the reasons for coverage denials, the right to appeal adverse determinations, payment under waiver of liability, and recourse against beneficiaries for unpaid claims. Furthermore, the decision below flies in the face of long-standing decisions by this Court which mandate specific procedural protections for Medicare providers. The Court of Appeals' decision also conflicts with the rulemaking requirements of the Administrative Procedure Act as articulated by this Court.

III. STATEMENT OF THE CASE

A. Part B of the Medicare Program

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, commonly known as "Medicare", consists of two parts. Part A provides insurance protection against the costs of inpatient hospital and related post-hospital services, home health

care, and hospice care for individuals who are 65 or over or who are otherwise entitled to Medicare benefits. 42 U.S.C. §§ 1395c - 1395i - 4. Part B of the Medicare program is entitled "Supplementary Medical Insurance Benefits for the Aged and Disabled." It furnishes insurance coverage for a broad spectrum of health and medical services including, *inter alia*: certain physicians services and supplies and services incident to physicians' services; physical therapy, speech pathology, and occupational therapy services; outpatient hospital services; rural and community health clinic services; ambulatory surgery; care provided by comprehensive outpatient rehabilitation facilities; and x-ray, laboratory, and other diagnostic tests. 42 U.S.C. §§ 1395k - 1395x(nn).

Medicare Part B is a substantial federal program. Approximately 32.6 million individuals currently participate in the Medicare supplementary insurance program and in excess of $42 billion in Part B benefits are paid out annually. Physical therapists, speech pathologists, occupational therapists, physicians and other health professionals represented by the *Amici* herein submit millions of Part B claims annually.

Part B is administered by the Secretary who is authorized by statute to contract with private insurance carriers to review and pay, on the Secretary's behalf, all Part B claims.[2] 42 U.S.C. § 1395u. These carriers act as the Secretary's agents for this purpose (42 C.F.R. § 421.5) and the Secretary pays the carriers' costs of administering the Part B claims process. 42 U.S.C. § 1395u(c).

B. Part B Claims Review and Adjudication

Medicare carriers review, adjudicate, and pay Part B claims pursuant to procedures precisely specified in the Medicare statute and the Secretary's regulations. The procedures, which guarantee providers the right to individualized factual deter-

[2] Under certain circumstances, some Part B providers have their claims reviewed and paid by fiscal intermediaries rather than carriers.

minations, notice, and appeal, find their genesis in the claims adjudication process formulated over 45 years ago for Title II of the Social Security Act. *See* 42 U.S.C. § 405(a),(b),(g) as incorporated by 42 U.S.C. §§ 1395ff, 1395ii. These procedures were adopted for Medicare beneficiaries for Part A coverage determinations in 1965. Pub. L. No. 89-97, § 102, 79 Stat. 286 (1965), (codified at 42 U.S.C. § 1395ff(b)). *See also* 42 C.F.R. § 405.701. They were put in place for providers of services under Part A in 1972. Pub. L. No. 92-603, § 213(a)(1972) (codified at 42 U.S.C. § 1395pp(d)). While Part B providers had access to the initial determination, notice, and fair hearing procedures prior to 1986, the opportunity for administrative law judge hearings and judicial review of Part B claims was not extended until 1986. Pub. L. No. 99-509, § 9341(a) (1)(A-D), 100 Stat. 1874 (1986) (codified at 42 U.S.C. § 1395ff(a),(b).

The statutory basis for Part B provider rights to individual factual determinations and administrative and judicial review resides in 42 U.S.C. § 1395ff which states in pertinent part: "The determination of whether an individual is entitled to benefits under Part A or Part B..., and the determination of the amount of benefits under Part A or Part B..., shall be made by the Secretary in accordance with regulations prescribed by him."

When a beneficiary or provider of services submits a claim for payment, the carrier makes an initial determination whether it should be paid. 42 C.F.R. § 405.803. The initial determination involves deciding whether the services were covered by Medicare; whether the services were medically necessary; whether the charges for services were reasonable; and whether the beneficiary or provider "knew or could reasonably have been expected to know that such items or services were excluded from coverage." 42 C.F.R. § 405.803(b). The very nature of these determinations demand a highly individualized analysis of the facts concerning the beneficiary and the claim.

A party dissatisfied with the initial decision may request the carrier to review the determination. 42 C.F.R. § 405.807. The carrier reviews the claim on the basis of the evidence in the record and issues a separate determination affirming, reversing, or revising the initial determination. 42 C.F.R. § 405.810.

A party has the right to a hearing before a carrier hearing officer if the carrier's decision on review is not favorable and the amount in controversy is at least $100.00. 42 C.F.R. § 405.820. The hearing is on the record (42 C.F.R. § 405.833) and the provider of services or the beneficiary may appear at the hearing and present testimony and other evidence. 42 C.F.R. § 405.830. The hearing officer must make a written decision based upon the evidence in the hearing record. 42 C.F.R. § 405.834. The decision is final and binding on all parties (42 C.F.R. § 405.840) unless it is reopened and revised pursuant to 42 C.F.R. § 405.841.

A claim dispute may be appealed to an administrative law judge ("ALJ") provided that the amount in controversy exceeds $500. 42 U.S.C. § 1395ff. At an ALJ hearing, a party is entitled to present its case through documentary evidence and witnesses. 20 C.F.R. § 404.950. A transcript of the testimony and exhibits, together with all other papers submitted in the case, forms the exclusive record upon which the ALJ's decision must be based. 20 C.F.R. § 404.951.

An adverse decision by an ALJ may be appealed to the Appeals Council (20 C.F.R. § 404.967) or, alternatively, the Appeals Council itself may decide to review the decision. 20 C.F.R. § 404.969. Appeals Council review is predicated on the record before the ALJ as well as any new evidence accepted by the Council. 20 C.F.R. § 404.976(b). The Appeals Council has the authority to render a final decision on behalf of the Secretary which is then subject to judicial review. 20 C.F.R. § 404.981. If the Appeals Council declines to take review, the ALJ decision

becomes the final decision of the Secretary and is subject to judicial review. 20 C.F.R. § 404.981.

42 U.S.C. § 1395ff provides for judicial review of Medicare Part B claims where the amount in controversy is at least $1,000. 42 U.S C. § 1395ff(b)(2)(B).

C. The Secretary's Use of Sample Adjudication

In this case, the Secretary abrogated the rights of three home health agencies to individualized factual determinations, notice and appeal under Part A by utilizing a sampling procedure to readjudicate and deny thousands of claims that had previously been determined to be covered pursuant to the Secretary's claims review procedures. The Secretary's sampling procedure operated as follows: he conducted a post-payment review of a small sample of each provider's claims and then extrapolated the percentage of newly denied claims to the remaining universe of unreviewed claims. This methodology resulted in the readjudication of the claims not included in the sample without affording the providers the procedural rights to which they were entitled. The Secretary did not even identify the specific claims in the universe which were disallowed.

Although this case involves only Part A of Medicare, its disposition will have an identical impact on Part B providers such as those represented by the *Amici*. Indeed, the Secretary has in the past employed statistical sampling against Part B providers. *See Mile High Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988). The Court of Appeals below recognized that the decision in *Chaves* would govern Part B providers:

> Although Part B is somewhat different from Part A, there is no essential difference in their recoupment powers for coverage overpayments. Furthermore, amendments added in 1986 extended Part A claims adjudication procedures to Part B claims as well.

> (Consequently, a contrary holding on the statutory question in this case could imperil sample adjudication under Part B).

Chaves County Home Health Service v. Sullivan, 931 F.2d 914, 918-19 (D.C. Cir. 1991).

D. The Decisions Below

The Court of Appeals rendered its decision in this case on April 26, 1991. The court held that: (1) sampling procedures for recoupment of overpayments to home health care providers do not violate the Medicare statute; (2) sample adjudication does not violate procedural due process; and (3) the sample audit procedures were not impermissibly retroactive and were not in violation of Administrative Procedure Act requirements. *Chaves*, 931 F.2d at 914.

The court's opinion observed that the question whether sample adjudication is an unreasonable interpretation of the Medicare statute is "close." *Chaves*, 931 F.2d at 923. The Court of Appeals also agreed with the following contentions advanced by the providers: (1) the language and overall structure of the Medicare statute and regulations require individualized factual determinations (*Chaves*, 931 F.2d at 917, 919-20 and 922-23); (2) Medicare providers have the same right to individualized factual determinations as beneficiaries (*Chaves*, 931 F.2d at 917, 919 and 921); and (3) there is no authority in the statute, its legislative history, or in the Secretary's regulations to support the use of sample adjudication. *Chaves*, 931 F.2d at 916 and 922.

Having recognized these principles, however, the court misapplied them. First, the court found that although the statute provides for individualized factual determinations, it does so only for "pre-payment review" and not "post-payment review." Accordingly, the court reasoned, sample adjudication does not conflict with the statutory mandate for individualized claims

review. *Chaves*, 931 F.2d at 917, 921. Although it conceded that neither the statute, its legislative history, nor the regulations provide a basis for differentiating between the adjudication of pre-payment and post-payment claims, the court insisted, absent an explicit prohibition of sampling, that it must defer to the Secretary's general authority to recoup overpayments.

The court also ruled that the different standard of individualized review for post-payment claims met the Medicare statute's requirements for individualized adjudication of claims because it gives claimants the opportunity to challenge the denials of specific claims within the sample. *Chaves,* 931 F.2d at 922-23.

The providers in *Chaves* had asserted that HCFA Ruling 86-1, the ruling which sets out HCFA's procedures for administering sample adjudication, was invalid because it was not promulgated pursuant to the Administrative Procedure Act, 5 U.S.C. § 553 *et seq.* ("APA") and was impermissibly retroactive. The court rejected these arguments finding that the ruling was merely an explanation of a "long-standing and well-established" practice, not an announcement of a new scheme which would require prospective application or compliance with the APA notice and comment requirements. *Chaves*, 931 F.2d at 923.

IV. REASONS FOR GRANTING THE WRIT

A. Statistical Sampling Abrogates Rights Granted to Providers By Statute and Regulation

As explained in detail above, *supra* at 7-10, the Social Security Act and the Secretary's regulations thereunder guarantee Part B providers the absolute right to a comprehensive multi-step administrative process for the review and adjudication of Medicare claims: (1) an initial determination on each beneficiary's claim; (2) carrier review of an adverse initial

decision; (3) a carrier fair hearing in the event the review decision is unfavorable on claims in excess of $100; (4) an appeal to an ALJ if the amount in controversy exceeds $500; and (5) review of the ALJ decision by the Appeals Council. Judicial review of Part B cases is available if the amount in controversy is at least $1,000. These procedural rights exist for every Part B claim.

This procedural scheme is triggered by a single event – the denial of a Medicare Part B claim. For this reason, each step of the process necessarily entails an assessment of highly individualized facts – *e.g.*, whether the services in question were medically necessary given the beneficiary's medical condition, the nature and number of treatments received, the likelihood that the services will improve the patient's condition, pre-existing diseases or injuries, and the effectiveness of the provider's services, etc. Similarly, numerous facts specific to the beneficiary and provider must be examined in determining whether the cost of the service was reasonable.

Sample adjudication operates in fundamental conflict with the principles of individualized review which are clearly articulated in the statute and implementing regulations. As a practical matter, statistical sampling completely circumvents the comprehensive Part B claims review process described above. *See supra* at 6-10.

Except for the claims in the sample, there is no individualized review of any other claim in the universe of claims which will be used to calculate the Medicare overpayment amount. By the very nature of statistical sampling, a Part B provider is accorded all of its procedural rights in only a relatively small portion of its cases. For example, if the Secretary took a sample of 350 claims from 10,000 claims that the provider submitted in a given year and then used the percentage denial rate for the sample to calculate a recoupment amount for the entire universe, the provider would have been deprived of its right to individual-

ized factual determinations, notice, and appeal for 9,650 of its claims. Neither the Social Security Act nor the Secretary's regulations specify that these provider rights need only be afforded in some of the provider's claims cases.

The Court of Appeals attempted to rationalize the deprivation of procedural rights inherent in sample adjudication by asserting that there was a difference in the procedural rights which attach to pre-payment claims review and those which govern post-payment review.

> HHS has not, in fact, suspended individualized determinations and substituted sample adjudication review of payment claims (*a decision that would be inconsistent with the statute*); instead, the Department has supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review of providers suspected of overbilling.

Chaves, 931 F.2d at 917. Emphasis supplied.

The court's argument is specious for several reasons. First, neither the statute nor the Secretary's regulations expressly or implicitly differentiate between the Part B provider rights available on pre- and post-payment review. Quite to the contrary, the statute and regulations clearly afford a provider the full panoply of procedural protections regardless of when the review occurs. Second, the court's argument conveniently ignores the practical effect of sample adjudication. When sampling is used on post-payment review, all of the initial favorable determinations for each of the claims in the universe made on pre-payment review are voided. In a very real sense, therefore, sample adjudication renders the pre-payment protections irrelevant and sampling becomes the only mechanism by which denied claims are adjudicated. Third, if the Court of Appeals is correct in its finding that Part B providers enjoy little protection on post-payment review, the Secretary might well refrain from denying claims on pre-payment review – when providers may exercise

all of their procedural rights — and instead deny the claims on post-payment review where the court below says providers have far more limited rights.

Sample adjudication deprives Part B providers of another crucial right — the right to receive payment for their services. In the event that Medicare denies payment for a claim on the ground that the service was not medically necessary, the provider has the legal authority to seek payment from the patient pursuant to state law. This right has long been recognized by the Secretary[3], Congress[4], and the courts.[5] Statistical sampling renders these rights unenforceable, however, because the provider has no way of identifying the individuals in the universe of unsampled claims whose claims have been denied.

Statistical sampling also disregards the Secretary's duty to furnish detailed reasons for denial whenever a claim is not paid. This information is provided so that the claimant can make a reasonable decision as to whether to pursue administrative or judicial review. Such information is non-existent where sampling is used and so, therefore, is any record upon which an appeal can be predicated. More importantly, this individualized decision-making furnishes beneficiaries and providers with guidance as to those services which will be paid and those which Medicare will not cover. In this way, providers and beneficiaries can avoid submitting claims for which payment is unavailable from Medicare.

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[3] HCFA Ruling 83-1 (1982).

[4] S. Rep. No. 1230, 92d Cong., 2d Sess. 294 (1972).

[5] *Highland District Hospital v. Secretary of HHS*, 676 F.2d 230, 238 (6th Cir. 1982).

B. The Decision of the Court of Appeals Contravenes Long-Standing Holdings By this Court.

The formal Medicare claims adjudication process available to Part B providers arises out of, and is substantially similar to, the claims adjudication process extant in Title II of the Social Security Act as early as 1947. *See* discussion *supra* at 6. This Court, on numerous occasions, has ruled that Title II requires individualized factual determinations, notice of those determinations, and administrative and judicial review. *See e.g.*, *Sullivan v. Zebley*, 493 U.S. 521, 110 S. Ct. 885, 888 and 890 (1990); *Heckler v. Campbell*, 461 U.S. 458, 468 (1983); *Richardson v. Perales*, 402 U.S. 389, 394-98 (1971); and *Bowen v. Yuckert*, 482 U.S. 137 (1987). *Zebley* is particularly instructive in this regard because it states that the Social Security Act's claims adjudication process clearly contemplates individualized functional assessments, because only such review can address the:

> infinite variety of medical conditions and combinations thereof, the varying impact of such conditions due to the claimant's individual characteristics, and the constant evolution of medical diagnostic techniques.

Zebley, 110 S. Ct. at 896.

The progeny of the Title II claims adjudication process — the Medicare Part A and Part B procedures — demand the same review of individualized facts throughout the review process, running from initial determination through judicial review. As explained above, *supra* at 8-9, Medicare Part B claims adjudications necessarily entail highly unique and specific facts for each beneficiary including, *inter alia*, the person's medical condition, medical history, course of treatment, prognosis, etc. Therefore, the Court of Appeals, in ruling that the Secretary may circumvent the multi-step review process for Part B claims, renounced

over two decades of decisions by this Court holding that individualized factual determinations, notice, and administrative and judicial review must be provided under Title II of the Social Security Act.

C. The Decision of the Court of Appeals Conflicts With the Rulemaking Requirements of the Administrative Procedure Act as Articulated by this Court.

In its decision, the Court of Appeals found that sample adjudication was a "long-standing practice" of the Secretary and not "a brand new scheme ushered in by HCFA Ruling 86-1." *Chaves*, 931 F.2d at 923. For this reason, the court ruled that HCFA Ruling 86-1 was an interpretive rule which did not have to be promulgated pursuant to the requirements of the APA. This decision is erroneous and squarely conflicts with the APA's requirements as recognized by this Court.

This Court has carefully delineated the standards which are to be utilized to determine whether an agency rule is "substantive" or "interpretive." A substantive rule is one that is "binding" or has the "force of law" and which "affects individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 99 S.Ct. 1705, 1717-1718 (1979). *See also Morton v. Ruiz*, 415 U.S. 199, 94 S. Ct. 1055, 1074 (1974). An interpretive rule, by contrast, is not binding, has no future effect, and is merely a statement of what the statute or regulation has always meant in the opinion of the agency issuing the interpretation. *First State Bank of Hudson County v. United States*, 599 F.2d 558 (3rd Cir. 1979), *cert. denied* 444 U.S. 1013 (1980).

Under these standards, HCFA Ruling 86-1 is clearly a substantive rule which should have been promulgated pursuant to the APA. The ruling affects providers rights by depriving them of the comprehensive multi-step administrative procedure for Medicare claims review. It is also binding on the parties because it is used to deny claims on post-payment review which

had been approved for payment on pre-payment review. Furthermore, since the statute and regulations contain no authority for the use of sampling, it stretches credulity to argue that HCFA Ruling 86-1 only restates what the law already provides.

A substantive rule which must be promulgated pursuant to the APA can also arise out of an agency's change in administrative adjudication procedures. In *National Motor Freight Traffic Ass'n v. United States*, 268 F. Supp. 90 (D.D.C. 1967), *aff'd*, 393 U.S. 18 (1968), this Court affirmed a decision which held that an agency rule establishing a scheme for administrative adjudication constituted a substantive rule subject to the APA's notice and comment procedures. The district court had reviewed a series of Interstate Commerce Commission rules which established informal adjudication procedures for carrier overcharge claims. Rejecting the argument that the rules merely established procedures for implementing substantive statutory rights, the court of appeals held that the agency's decision to establish procedures for administrative adjudication was the type of ruling that the APA required to be open to public participation. *National Motor Freight*, 268 F. Supp. at 95-96; *see also* 1 K. Davis, Administrative Law Treatise § 6.29 (2d ed. 1978) (describing *National Motor Freight* as "the most authoritative decision" on the scope of 5 U.S.C. 553(b)(A)).

National Motor Freight is particularly instructive in this case because sample adjudication suspends or circumvents the comprehensive individualized claims review procedures mandated by the Medicare statute and the Secretary's regulations. In so doing, statistical sampling, as provided for in HCFA Ruling 86-1 radically alters the administrative adjudication procedures for Medicare claims. *National Motor Freight* teaches that any such change must be published pursuant to the APA.

The Court of Appeals' only rationale for labeling HCFA Ruling 86-1 an interpretive rule was that sample adjudication was a "long-standing practice" of the Secretary. This finding is

erroneous. Sample adjudication is neither a common nor long-standing practice in Medicare claims cases. Prior to *Chaves*, there is no reported instance of the Secretary's use of sampling to suspend a provider's procedural rights to individual factual determinations, notice, and appeal in Part A cases. Furthermore, the court could point to only one case, *Mile High Therapy Centers*, in which sample adjudication supplanted Part B claims review procedures. This case is inapposite, however, because it involved a sampling methodology utilized by the Secretary prior to the time when the ALJ and judicial review provisions for Part A were extended to Part B providers. Simply put, there was no evidence before the court below that sample adjudication is a long-standing practice.

HCFA Ruling 86-1 is clearly not an interpretive rule. "Interpretive rules are those which merely clarify or explain existing law or regulations." *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir. 1983). They are non-binding and do not "foreclose alternative courses of action or conclusively affect rights of private parties." *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980). The use of statistical sampling interferes with and suspends the provider's rights to initial determinations, notice, appeal, and waiver of liability under the Medicare Act and regulations. For this reason, HCFA Ruling 86-1 did not merely explain existing law; it created new law which foreclosed providers' administrative procedure rights and in so doing conclusively affected their rights.

A substantive rule is invalid if it is not promulgated pursuant to the procedural requirements of the APA. *Buschmann v. Schweicker*, 676 F.2d 352 (9th Cir. 1982). *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979); *Linoz v. Heckler*, 800 F.2d 871, 878 (9th Cir. 1986); *In re Home Health Care, Inc. v. Bowen*, 639 F. Supp. 1124 (D.D.C. 1986). Because the Secretary failed to comply with the APA requirements in promulgating HCFA Ruling 86-1, that ruling is invalid and cannot provide authority

for the use of sampling methodologies in Medicare overpayment cases. The Court of Appeals' finding to the contrary is in error.

V. CONCLUSION

For all of the reasons set out above, this Court should grant the Petition for a Writ of Certiorari.

Respectfully submitted,

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(5)

NO. 91-674

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

Chaves County Home Health Services, Inc., et al.

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v.

Louis W. Sullivan, M.D.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY TO RESPONDENT'S OPPOSITION

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The critical importance of the issues presented to the Court is recognized by both parties and amici. Petitioners assert that Medicare beneficiaries, providers of care, and the Medicare system itself face great harm if the Secretary is allowed to substitute sample adjudication of claims for the Congressionally mandated and traditionally utilized system of individual claims review.

Amici, representing the national interests of virtually every element of health care -- physicians, hospitals, therapists, nursing facilities, and home health care providers -- forcefully outline the grievous harm that is inflicted through sample adjudication. Uniformly these provider groups express that sample adjudication deters them from providing needed care to Medicare beneficiaries, subjects them to severe financial damage, and eliminates rights guaranteed by statute including a meaningful opportunity for relief on appeal.

Respondent contends that the use of sample adjudication is crucial to the operation of the Medicare program. Accordingly, all parties agree that the issues presented in this petition are of vital importance to Medicare and the health care system.

Accordingly, there is no dispute that this case involves an important issue of federal law of major significance to Respondent, as well as the entire health care community. Rule 10.1(c) of the U.S. Supreme Court.

ARGUMENT

The Brief For The Respondent In Opposition raises serious issues which necessitate this reply. Respondent has mischaracterized the issues in this case, obscured the unfairness of sample adjudication, and misstated the longstanding practice and process of claims adjudication.

A. Individualized coverage determinations must precede the Medicare overpayment recoupment process.

This matter concerns exclusively the process of coverage determinations for claims submitted to the Medicare program under 42 U.S.C. § 1395ff(a). It does not involve, as claimed by the Respondent, the power and process to recoup alleged Medicare overpayments after a lawful coverage determination has been issued.[1] Likewise, the reasonableness of sampling in the abstract context is not challenged. Instead, the core issue is whether Respondent's sample adjudication policy conflicts with the minimum statutory due process requirements for making coverage determinations in Medicare Part A claims.

Respondent avoids the true nature of this case because to recognize that coverage determinations must precede any calculation and collection of an overpayment would be fatal to his position.

The Court of Appeals concluded, and the Respondent does not contest, that 42 U.S.C. § 1395ff(a) requires individualized coverage determinations on all claims for both Medicare beneficiaries and providers. Respondent has not, and cannot, offer any support for the Court of Appeals' mysterious distinction between pre-payment coverage determinations (which the Court finds must be individualized) and post-payment coverage determinations. It is most notable that Respondent fails to reference any statutory authority, for direct or interpretative power, to engage in sample adjudication of coverage determinations.

The language and structure of the Medicare statutory scheme demonstrates that 42 U.S.C. § 1395ff(a) is the

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[1] A critical defect in the formulation of the issue by Respondent is that he presumes the existence of an overpayment without first engaging the mandate process of coverage determinations.

exclusive source of authority for the Secretary's process of issuing coverage determinations. While other provisions establish standards for coverage (e.g. 42 U.S.C. § 1395y(a)(1)), limitations on liability (e.g. 42 U.S.C. § 1395pp), and the Secretary's power of recoupment (42 U.S.C. § 1395gg), all such substantive authority must be channeled through the process of determination required under 42 U.S.C. § 1395ff(a). As the Court of Appeals correctly held, § 1395ff(a) requires individualized coverage determinations. Respondent is authorized to act solely under 42 U.S.C. § 1395ff(a) and regulations promulgated thereunder, 42 C.F.R. § 405.701 *et seq.*, for the process of issuing the resulting coverage determinations.

Respondent contends that petitioners do not explain why the Act's procedural provisions governing pre-payment coverage determinations extend to post-payment recoupment audits. (Resp. 10). However, it is Respondent who cannot explain the authority for a *distinct process* given the language of 42 U.S.C. § 1395ff(a) which extends to all coverage determinations and sets out the exclusive authority for the determinations process.

Providers have the right to rely upon the finality of a Medicare coverage determination unless it is subject to reopening under 42 C.F.R. § 405.750. Respondent acknowledges that "reopening" of the initial claim determinations was necessary in order for him to assert the existence of any overpayment. (Resp. 5). Respondent's own regulations and instructions clearly state that the rights to individualized claim determinations and appeal which apply when claims are initially adjudicated also apply when that initial determination is reopened and revised. *See* Brief of Amici Curiae, American Hospital Association, *et al.* p. 9. Nevertheless, Respondent allows for the exercise of these rights with only a small percentage of the Medicare claims while acting to affect 100% of those claims. The Court cannot assume the drastic abrogation of important procedural rights without expressed intent.

Remarkably the Respondent's regulations are fully consistent with Petitioners' position, yet these regulations are also ignored by Respondent. For example, "a determination as to whether there has been an overpayment or underpayment of benefits paid under part A, and if so, the amount thereof" is considered an "initial determination" under 42 C.F.R. § 405.704, which was promulgated under the authority of 42 U.S.C. § 1395ff(a), *see* 42 C.F.R. § 405.701(a). If, as correctly held by the Court of Appeals, 42 U.S.C. § 1395ff(a) requires individualized determinations, then the Respondent's overpayment decision must be subject to the same process afforded claims at the pre-payment stage.[2]

The Respondent's recognition that the Medicare Act provides no explicit or implicit authorization for sample adjudication leaves him to justify the elimination of individualized determinations on grounds of administrative burden and convenience. (Resp. 14.) However, Respondent also concedes that all coverage determinations within Medicare, for both beneficiaries and providers, are subject to the same process. (Resp. 10.) If the same statutory and regulatory provisions apply, then Respondent must believe that sample adjudication is allowed for prepayment determinations, a position which is at odds with the Court of Appeals findings; Pet App. 6a.

Further, Respondent's position would justify that abrogation of procedural rights for beneficiaries as well. Given that 42 U.S.C. § 1395ff(a) applies equally to providers and beneficiaries, Medicare would be authorized to ignore the procedural protections designed for beneficiaries, if the determination is rendered on a post-payment basis.

Respondent's claim that individualized determinations are not "feasible" conflicts with a judgement already made by Congress. Congress has already balanced the rights to individualized determinations and appeals in the design of § 1395ff. Respondent concedes that the procedural rights must

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[2] Respondent ignores the fact that payments to providers "shall be regarded" as payment to individuals. 42 U.S.C. § 1395gg (a).

be provided for pre-payment of determinations. Such procedures are equally feasible for post-payment adjudication. The jurisdictional amount in controversy requirements set out in 42 U.S. C. § 1395ff present solid evidence that Congress has balanced the need for administrative and judicial review on individual claims against the burden of affording those rights. It set minimum levels of $100 and $1000 for fair hearings and judicial review respectively, amounts which are to be determined with respect to individual claims.

The claims adjudication process set out in 42 U.S.C. § 1395ff is based on the process prescribed by Title II of the Social Security Act, 42 U.S.C. § 405. This Court has consistently found that Title II requires individualized determinations and appeals. (Amici p.6-7). Likewise, as noted by amici, the Title II and Title XVIII claims adjudication process has been amended numerous times since enactment without "the slightest indication that the Secretary is authorized to adjudicate claims" on a sample basis. Amici AHA, et al. 13-14 fn 16. It is not conceivable that Congress could have established the low thresholds for appeal and intended to allow for sample adjudication without so stating over the last twenty-five years of Medicare amendments to the appeals provisions.

B. Sample adjudication denies petitioners important rights to payment for services.

Throughout this case, both the Respondent and the Courts have failed to recognize the harm brought upon providers and beneficiaries through sample adjudication. It is obvious that sample adjudication deprives parties of individualized notices, determinations and rights of appeal. In addition, sample adjudication directly blocks health care providers from obtaining payment for services.

The right to obtain payment for services is evidenced by Medicare policy which states that a provider can obtain payment from alternative third party payors. Longstanding Medicare policy specifically states that the waiver of liability provision of 42 U.S.C. § 1395pp does not apply to third party payors. A provider determined liable under 42 U.S.C. §

1395pp "may seek payment from a third party payor other than a liability insurer without being subject to recovery action that could occur if it sought payment from the beneficiary." Medicare Intermediary Manual, ¶ 3432.2E; Medicare Home Health Agency Manual, § 262.2E.

Many Medicaid programs and third party insurers cover home health services that are not covered under Medicare. These payors provide coverage secondary to Medicare. With sample adjudication, home health agencies cannot document Medicare noncoverage and bill other appropriate pay sources. While the provider can document the individual claims within the sample, it cannot even identify the claims within the universe that should also be subject to third party billing. The sample adjudication system offers no remedy which would allow providers a means to recover payments due from alternative payment sources since no Medicare coverage determination is issued for the anonymous individuals within the universe. The only way that a home health agency's right to seek payment can be preserved is through individualized determinations.

C. Sample Adjudication renders prepayment determinations a sham.

Respondent contests Petitioner's assertion that sample adjudication turns the guarantee of individualized pre-payment determination into a sham. However, the Court of Appeals' decision offers the complete license for that result. Presumably, each claim of the petitioners was subject to an individualized pre-payment review. However, many months or years after care was rendered and payment made by Medicare, along came sample adjudication which, for all intents and purposes, ignored the original individualized coverage determination. In practice and operation the sample determination was substituted for the actual review performed on the original claim. The individualized determination became a meaningless decision, a sham.

Under the system embraced by the Respondent, a cursory prepayment review can be performed on individual

claims, followed by sample adjudication the very next day. Within moments all the protections established by Congress -- individualized reviews, notice, waiver of liability, rights of appeal -- disappear, replaced by a system the Respondent believes to be the only feasible system, despite choices to the contrary made by Congress. Through this subterfuge, the Respondent simply defeats the statutory due process rights of providers, substituting sample adjudication for the mandated individualized determination.

D. Sample Adjudication is unfair and inaccurate.

Respondent has the audacity to claim that sample adjudication yields fair and accurate results. Resp. 13. In reality, sample adjudication destroys health care providers who have committed no offense and blocks providers from their rights to a fair appeal. It is Respondent's policy and practice to recoup any alleged overpayments calculated from sample adjudication well prior to any opportunity of the provider to utilize rights of appeal. Further, Respondent has closed the doors to administrative and judicial relief by claiming that the "amount in controversy" necessary to establish jurisdiction is based upon the individual claim within the sample, rather than the extrapolated effect of the claim in sample adjudication. As such, Respondent has denied Petitioners access to fair hearings and judicial review where the individual claim did not pass the jurisdictional amount in controversy although far surpassing the threshold through the extrapolated projection.

Petitioners exemplify the unfairness and inaccuracy of sample adjudication. Alburqueque Visiting Nurse Service, after decades of providing high quality home health services, has closed and is in bankruptcy, unable to survive the Respondent's attack and obstructions to due process. Chaves County Home Health Services survived, yet it continues to challenge the remaining claim determinations after nearly seven years. Unrefuted evidence demonstrates that honest home health agencies are driven to ruin by sample adjudication.

Sample adjudication only magnifies the errors of Respondent's agents that seek bounties from innocent

providers who are subjected to unsubstantiated tips of program abuse. Respondent concedes that the coverage determinations issued through sample adjudication were generally flawed, noting that Petitioners "largely prevailed" in the appeals process. (Resp. 4-5.) It is a process which is not only unfair, it simply does not make sense. It is also a destructive practice that Congress has prohibited.

E. Sample adjudication is not a longstanding practice.

Respondent's argument that HCFA Ruling 86-1 is not subject to notice-and-comment rulemaking is based upon a fictionalized account of an alleged longstanding practice.

First, Respondent mischaracterizes Mount Sinai Hospital of Greater Miami v. Weinberger. 417 F.2d 329, modified, 522 F.2d 179 (5th Cir. 1974), cert. denied, 425 U.S. 935 (1976) as "upholding [the] Secretary's use of a sampling post-payment audit to recoup $6.3 million." (Resp. 16.) In reality, no court in Mount Sinai Hospital ever reviewed or addressed the legality of sample adjudication. At best, Mount Sinai Hospital represents an isolated incidence of sampling which took place prior to the enactment of due process protections for providers in 1972 through 42 U.S.C. § 1395pp (d) which accorded providers the same rights guaranteed Medicare beneficiaries and Social Security beneficiaries under Titles II, XVI, and XVIII.

Respondent's statement that sample adjudication "has not been a recurring source of controversy in the sixteen years" since Mount Sinai Hospital is indicative of the fact that sampling is not a consistent and longstanding mode of coverage determinations. With the attention this issue has drawn -- amici represent virtually all of the health care industry -- one would certainly expect a challenge to such practice earlier if such practice had been longstanding.

The provider group amici agree that "sample adjudication is neither a common nor longstanding practice in Medicare claims cases." Brief of Amici Curiae National Association of Rehabilitation Agencies, et al., 19; see also,

Brief of Amici Curiae American Hospital Association, et al., 17-18. Since these groups represent the entire health care industry, it is likely they would be aware of the application of sample adjudication in Medicare claims.

Respondent's assertion that sampling is a longstanding practice is in conflict with the General Account Office which indicated that the Secretary had no sampling adjudication process for Medicare Part A. The Secretary then rejected the GAO's recommendation to develop such a process, stating that "home health agencies have certain rights which would not be available under the [sampling] procedure. AHA Am. App. 2C.

Beyond Mount Sinai Hosp., the Respondent cites several Medicare manual provisions that allegedly pre-date the issuance of the contested HCFA Ruling 86-1.[3] Resp. 16. However, Petitioner believes that these citations reference erroneous dates, since it strains credibility to accept that the GAO would suggest the development of sampling policy in 1986 if one existed since 1975.

If the Court of Appeals factual finding that sample adjudication represents a longstanding interpretation by the Respondent is corrected, it's holding on the Administrative Procedures Act, 5 U.S.C. § 553, claim is without any support.

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[3] The Secretary's first reference to these policies occurred in response to Appellant's Petition for Rehearing And Suggestion For Rehearing En Banc. Despite discovery requests for such information over the years, Petitioners have never been supplied these provisions by the Secretary.

CONCLUSION

This petition presents issues of vital importance affecting fundamental rights under the Medicare program. All elements of the health care industry are affected by the Respondent's use of sample adjudication. Respondent tacitly concurs that the matters at issue in this case are crucial. Accordingly, Petitioners respectfully request that the Court grant review.

Administrative developments with HHS further indicate the need for review of the petition by the Court. HHS is preparing a policy issuance which will implement the policy at issue in this case. It is anticipated that the policy will be released to Medicare intermediaries early this year. When the issuance occurs, the risk of harm to Medicare patients and provider will be magnified exponentially beyond that already suffered by the petitioners. The Court must address these issues now before greater harm can be inflicted.

Respectfully submitted,

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JAN 1992